

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
6 October 2005 (06.10.2005)

PCT

(10) International Publication Number
WO 2005/092410 A1

(51) International Patent Classification⁷: **A61M 5/158**

(74) Agent: **ZACCO DENMARK A/S**; Hans Bekkevolds Alle 7, DK-2900 Hellerup (DK).

(21) International Application Number:
PCT/DK2005/000189

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(22) International Filing Date: 21 March 2005 (21.03.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/556,863 26 March 2004 (26.03.2004) US
PA200400493 26 March 2004 (26.03.2004) DK

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*): **UNOMEDICAL A/S** [DK/DK]; Engmosen 1, DK-3540 Lyngø (DK).

(72) Inventors; and

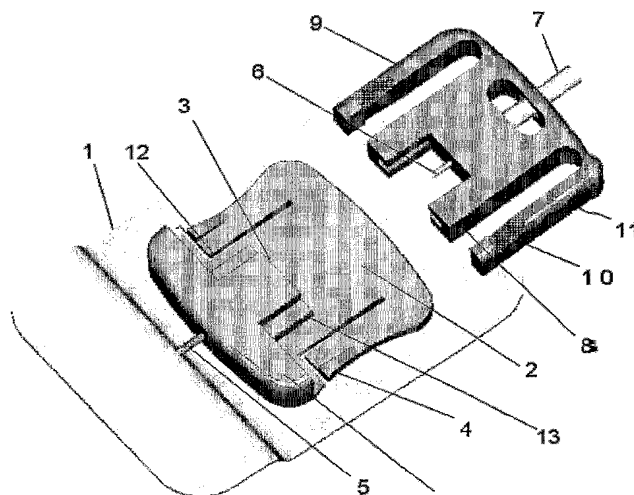
(75) Inventors/Applicants (*for US only*): **KORNERUP, Grete** [DK/DK]; Sandbakkevej 56, DK-4390 Vipperød (DK). **MOGENSEN, Lasse, Wesseltøft** [DK/DK]; Jacob Bulls Alle 100, 1., DK-2860 Søborg (DK). **GÖRANSSON, Magnus, Walter** [SE/SE]; Friisgatan 5A, S-21421 Malmö (SE).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INFUSION SET



(57) Abstract: The invention relates to an infusion set for an intermittent or continuous administration of a therapeutical substance, such as insulin. The infusion set comprises an infusion part (OB) for insertion into a patient and a connector (OA) for connecting the infusion part with a medical device through a tube (7), the connector being axially displaceable relative to the infusion part. The infusion part comprises an adhesive support (1), a base part (2) with a first set of guiding means (13) and at least two retention devices (4) for locking the connector to the infusion part, a cannula extending from said base part and being in fluid communication with a cavity which is optionally covered with a membrane, the cavity is further adapted to receive a second cannula extending from the connector, which second cannula is in fluid communication with the tube.

WO 2005/092410 A1

Infusion Set

The technical field

5 The invention relates to an infusion set for an intermittent or continuous administration of a therapeutical substance, such as insulin. An infusion set comprises an infusion part with a cannula to penetrate the skin of a person and a connector for connecting the infusion part with a medical device preferably a medical delivery device such as an insulin pump.

10

An infusion set has in its assembled form a substantially planar rear side and a relatively large width compared to its thickness, thus allowing it to lie flat on the patient's skin and thereby minimizing the discomfort of carrying the infusion set.

15

The infusion part is placed in the patient for a longer and not specified time period while the connector is supposed to be connected and disconnected from time to time. Hereby it is possible for the patient to disconnect from the medical device, move around and at a later point re-connect to the medical device. Further it is possible to shift between different medical devices using the same infusion part and thereby there is only need for one penetration of the skin which provides less discomfort to the patient.

20

Prior art

25

US-A-5.522.803 discloses an infusion set having an infusion part and a connector. The infusion part comprises a soft plastic cannula in liquid communication with a cavity for receiving a needle from a connector, two sloping guiding holes and two retention devices; and the connector comprises a cannula, two square guiding pins and two arms with a hooking part for gripping the retention device of the infusion part and operating in the main plane of the infusion part.

30

US-B1-6.572.586 discloses an infusion set for administration of a fluid to a subcutaneous layer and include a cannula housing adapted for mounting onto a patient's skin and a needle housing for connection to the cannula housing. The needle housing has a pair of flexible sidewalls and a resilient
5 band connected to the sidewalls. The resilient band is lockably engage able with the cannula housing thereby securing the housings together, and the resilient band is releasable from the cannula housing when pressing the sidewalls toward each other to deform the resilient band. A hollow needle extends out of a main body of the needle housing for delivering fluid to the
10 cannula from a fluid source. The walls of the needle housing extend beyond a distal end of the hollow needle to prevent needle contact with contaminated surfaces an inadvertent injury.

In both of these infusion sets two arms are formed along the sides of the
15 connector part and the movement performed to unrelease the connector from the infusion part is in both cases pressing the two arms together. Compared to these to constructions the present invention is of a more simple form and also the locking mechanism according to the invention allows for the user to actually see when the arms are unlocked, especially if the infusion part and
20 the connector are toned in different colors.

Given that the infusion part is supposed to be connected and especially disconnected several times with the connector it is important that this operation is painless and simple to perform.

25

The object of the invention is to provide an infusion set with a coupling mechanism which can be connected and separated with as less discomfort to the patient as possible, and which infusion set is also easy for the patient to find out and to operate.

30

According to the invention there is provided an infusion set comprising an infusion part for insertion into a patient and a connector for connecting the infusion part with a medical device through a tube. The connector is axially

displaceable relative to the infusion part, said infusion part comprising an adhesive support, a base part with a first set of guiding means and at least two retention devices for locking the connector to the infusion part, a cannula extending from said base part and being in fluid communication with a cavity
5 which is optionally covered with a membrane, said cavity being further adapted to receive a second cannula extending from the connector, which second cannula is in fluid communication with the tube, a second set of guiding means adapted to fit with the first set of guiding means and at least two arms where the retention devices are extending from the upper surface
10 of the main surface of the base part and the arms comprise means corresponding to the retention means.

The above described infusion set is easier to disconnect and will seem safer to use for the patient than previously known infusion sets. All that is needed
15 to separate the connector from the infusion part is a slight simultaneous pressure on the two arms of the connector and the user will be able to see how the connection/disconnection between the infusion part and the connector takes place.

20 With the term cavity is meant the inner lumen of the cannula or the extension of the cannula.

In a preferred embodiment the connector is symmetrical both around the main plain of the connector and around the plane being perpendicular to the
25 main plane and being parallel to the central axis, thus allowing the connector to be connected to the infusion part no matter which of the main sides is facing upwards. This results in an easier operation of the infusion set.

The arms of the connector can appropriately be provided with gripping
30 means for getting a better grip of the connector. Examples of such gripping means could be but are not limited to rims, grooves, recesses, and a roughened surface optionally of another material than the connector itself, preferably recesses are used. This results in a safer and more comforting

operation of the infusion set since the risk that the fingers slip during handling resulting in unintended movements of the infusion part and the cannula is reduced.

- 5 In one embodiment of the invention the connector has a reduced material content e.g. in the form of at least one groove, preferably at least two grooves, placed where the arms are connected to the central part of the connector comprising the second set of guiding means (8), thus allowing the arms of the connector to move perpendicular to the base part while the
10 second set of guiding means are stationary. This makes it possible to disconnect the connector from the infusion part by lifting the arms instead of pressing them towards each other. Hereby it is achieved that connection/disconnection can be performed in a manner which at the same time reduces the stresses in the material during the operation, eases the
15 operation of the locking mechanism and reduces the patient's unpleasantness during the connection/release of the connector.

In another embodiment retention devices are positioned on a particularly flexible part of the base part. The flexible part can be provided by choosing
20 an appropriate material for the base part or by providing very thin parts of material between the retention parts and the center of the base part, but preferably the base part of the infusion part has at least two cuttings forming at least two flaps. The formed flexible parts are able to in an elastic manner to move out of the main plane of the infusion part. Hereby the same
25 advantages during connection/release as described above are obtained.

In a preferred embodiment the cannula of the infusion part penetrates the adhesive support, thus stabilizing the position of the infusion part relative to the point of skin penetration to an even greater extent. Further this
30 minimizes the risk that the cannula is accidentally withdrawn from the patient.

In a preferred embodiment the adhesive support is a plaster.

In a preferred embodiment the infusion part and the connector are made from two different plastics materials, such as two different types of polypropylene.

5 In a preferred embodiment there is a visual difference in the toning of the connector and the base part of the infusion part. Hereby it is achieved that it is easier for the patient to see the separation line between the two units resulting in an easier operation of the locking mechanism.

10 In a preferred embodiment the retention devices are in form of at least two steps placed on either the infusion part or the connector and a matching carving in the other part. Preferably the step has a side with a triangular shape thus forming the step as a sloping hill. Preferably the retention devices are placed on the infusion part and the matching carvings are placed in the connector's arms.

15 In a preferred embodiment the tube is a flexible plastics material which preferably is connected with the rest of the connector by means of glue.

20 Preferably the medical delivery device is a drug delivery device such as an insulin delivery device e.g. in the form of an insulin pump.

The cannula of the connector can be a hard cannula, preferably a metal cannula such as a steel cannula. Also the cannula of the connector can be made of a plastics material and/or being blunt.

25 In a preferred embodiment the cannula is a soft cannula preferably a soft cannula made of a plastics material. Preferred plastics materials for the soft cannula are materials which are sufficiently flexible to bend, when the patient moves and sufficiently rigid to avoid kinking, closing off the drug supply.
30 Further the material must be compatible with medical use i.e. irritation of the skin must be kept at a minimum, being non-toxic it must not decompose in the body, etc. Thermoplastic elastomers (TPE) are a type of material which fulfils these requirements. Examples of such useful elastomers are: polyester

ethers, ECDEL, styrene based TPE, olefin based TPE, urethane based TPE, ester based TPE, amid based TPE, polyolefins and silicone rubbers. In a preferred embodiment the material is selected from the group consisting of polypropylene, C-FLEX™, mixtures of C-FLEX™ and polypropylene, 5 LUPOLEN™ 1840H, LUPOLEN™ 3020D, PELLETHANE™ 2363-75D, PELLETHANE™ 2363-55D, TECOTHANE™ and CARBOTHANE™.

In a preferred embodiment the infusion part and the connector are made of polypropylene.

10

Given that the infusion part is supposed to be connected and especially disconnected several times with the connector it is important that the cannula of the connector is guided safely into the cavity of the infusion part and that the cannula in the disconnected situation is protected as much as possible. It 15 is therefore a further object of the invention to provide an infusion set with an improved guiding mechanism and with an improved protection of the connector cannula.

In a preferred embodiment the connector cannula is extending from the 20 central part of the connector and being placed in a withdrawn position relative to the front of the central part and at least one of the first set of guiding means comprises at least two stabilizing fins.

The above described invention provides an infusion set with an improved 25 protection of the cannula of the connector thus allowing the connector to be connected and disconnected from the infusion part more times than in the previously known infusion sets.

A lot of patients e.g. insulin patients have to or may desire to insert an 30 infusion device or to place a subcutaneous sensor or the like themselves. For some persons it is a troublesome process to perform the skin penetration themselves, they therefore need a device which assists them in this process thereby making the process less problematic.

The document US 2003/0225373 discloses an insertion device for inserting an infusion part or a sensor into a patient. The device comprises a housing, a coil spring, a safety device and part for angling the insertion into the patient.
5 However the apparatus is relatively complicated to manufacture industrially and further the device has to be loaded manually by the patient by a rather complicated procedure.

WO 03/026728 A1 discloses an injector device comprising a housing, a
10 spring, a slidable bar, a locking mechanism and a needle.

It is a further object of the invention to provide an improved insertion device which is easy to manufacture and which is suitable for being delivered in a loaded form or at least being easier to load. Especially elderly people who
15 can have some motor problems need an insertion device which exists in a pre-loaded form.

The advantage in essentially vertical insertion is that it is easier to control the dept of the needle penetration and thereby the dept of the cannula. This is
20 important in self-insertion of the infusion part.

In the following the invention will be described in further details with reference to the figures.

25 Figure 1 shows one embodiment of an infusion set where the infusion part and the connector are unified.

Figure 2 shows one embodiment of the infusion set where the infusion part and the connector are separated.
30

Figure 3 shows the same embodiment of the separated infusion set as in figure 2 from a different angle.

Figure 4 shows a second embodiment of a separated infusion set from a first angle.

5 Figure 5 shows the second embodiment of the infusion set from a different angle.

Figure 6 shows a first embodiment of an injector device separated from the infusion part.

10 Figure 7 shows the first embodiment of the injector device joined with the infusion part.

Figure 8 shows the first embodiment of the injector device joined with the infusion part.

15 Figure 9 shows the first embodiment of the injector device where the pivoting member is embracing the needle.

20 Figure 10 shows the first embodiment of the injector device in the loaded position.

Figure 11 shows the first embodiment of the injector device in the loaded position from a second angle.

25 Figure 12 shows a second embodiment of the injector device in a loaded and secured state.

Figure 13 shows the second embodiment of the injector device in a ready to use state.

30 Figure 14 shows the second embodiment of the injector device after insertion of the needle and before removing the injector from the infusion part.

Figure 15 shows the second embodiment of the injector device after separating the injector from the infusion part.

5 Figure 16 shows the second embodiment of the injector device after the pivoting arm has been positioned to embrace the needle.

Figure 17 shows the second embodiment of the injector device after the pivoting arm has been positioned to embrace the needle seen from another angle.

10

Figure 18 shows an infusion set placed on the skin.

Figure 19 shows the second embodiment of the injector device together with a credit card.

15

Figure 20 shows a third embodiment of the injector device.

Figure 21 A-D shows assembling of the infusion part and injector device according to the third embodiment.

20

Figure 22 A-B shows the third embodiment of the injector device prepared for insertion.

25 Figure 23 A-B shows the adhesive support of the infusion part hooked to the slidable member.

Figure 24 A shows the injector device after insertion with an infusion part and figure 24 B shows the injector device after insertion without the infusion part.

30 Figure 25 shows the third embodiment of the injector device after insertion and embracing the needle.

Figure 26 shows a third embodiment of an infusion part placed on a mounting pad with two separate pieces of release liner.

5 Figures 35 A-D and 36 A-D show the different steps when using the injector device for injecting the infusion part.

Fig. 1-3 illustrates an embodiment of an infusion set. The infusion set comprises an infusion part (0B) and a connector (0A). The infusion part (0B) comprises a base part (2) having a main plane which, when the infusion set is attached to a patient, is essentially parallel to the skin of the patient, and a shoulder part (2a) protecting the connector part (0A) from being released unintentionally. Said base part (2) comprises a first set of guiding means (13) which in this case has the form of two stabilizing fins. The base part further comprises two retention devices (4) extending from the upper surface of the base part in this case in form of two steps. Mounted on the inner surface of the infusion part is an adhesive support (1) which in this case is a plaster. A cannula (5) is extending from the base part (2) and is penetrating the adhesive support (1) being in fluid communication with a central cavity (3). The cannula (5) is preferably a soft cannula but could also be made of metal. The cavity (3) optionally being covered by a membrane is adapted to receive a second cannula (6) extending from the connector. In the embodiment shown in fig. 2-5 the second cannula (6) is extending from the central part of the connector and is placed in a retracted position relative to the front of the central part. In this embodiment the base part (2) has two cuttings (12) creating two flaps on which the retention devices (4) are mounted. The connector (0A) comprises two arms (9) having four carvings (10) adapted to fit with the retention devices (4). The connector (0A) is symmetrical around the main plane and around the plane perpendicular to the main plane and parallel to the main axis thus allowing the connector to match with the base part in two ways. The cannula (6) is in fluid communication with the tube (7) which provides the connection to a medical device such as an insulin pump. In this embodiment the central part of the connector has a second set of guiding means (8) in form of two grooves placed symmetrically around the

main plane of the connector. In this embodiment the connector further has gripping means (11) in form of recesses. The gripping means 11 are optional and can be selected from the group consisting of rims, grooves, recesses or a roughened surface optionally of another material than the connector itself

5

Fig. 4 and 5 show another embodiment of the invention where the connector has two grooves (14) which in this case are placed symmetrically around the main plane of the connector. However it is not necessary for the grooves to be places symmetrically around the main plane since they are not coupling with the infusion part.

10

Whether the infusion set is intended to be inserted manually or by an injector the infusion part (0B) and the connector (0A) are delivered to the user as two separate units in sterile packages. When inserted manually the infusion part (0B) will at delivery be combined with a needle unit with the same locking and guiding means (8) as the connector. The needle unit is provided with an insertion needle extending from the central front which insertion needle at delivery extends through and beyond the end of the cannula (5). The needle unit's only function will be to penetrate the user's skin where after the needle unit is removed and replaced with the connector (0A) leaving the cannula (5) subcutaneous.

15

20

The connector (0A) can be connected to a luer coupling member through the tube (7). Through the luer coupling it is possible to administer a suitable therapeutical substance, such as insulin from a pump. The connector can also be a sort of closing part with a suitable entrance for an inserting needle of a syringe. Such a closing part can stay in position for up till three days while the user can have medication, e.g. insulin injected through the entrance in order to reduce trauma to the skin caused by repeated penetration of the skin.

25

30

It is important for the user that it is easy to change i.e. to engage and to disengage the infusion part (0B) and the connector (0A) even when the user

has reduced dexterity. The present invention complies with this purpose as the movement used to unlock the infusion part (0B) from the connector (0A) is pressing the connector between the first finger and the thumb which is simple and easily performed movement. Also the oppositely directed forces from respectively the first finger and the thumb pushing toward each other, are not only used to unlock the device but is also used when pulling the connector away from the infusion part (0B). In order to make it easier to disengage the connector (0A) the arms (9) can be made very flexible, either by choosing a soft and flexible material or by making the fastening of the arms (9) to the central part more or less rigid e.g. by varying the size of the grooves (14) on the shoulder of the connector (0A).

Although the arms (9) are very flexible the danger of accidentally pulling the connector away from the infusion part when positioned on the skin of the user is quite small as the device has to be exposed to a simultaneous pressure from both sides.

Another advantage of the invention according to the present invention is that only a very small amount of material need to be used when producing the infusion part. The infusion part (0B) can be reduced to:

- a slim central part comprising the cannula (5), the cavity (3) and guiding means (13),
- a shoulder part (2a) connected to the central part and protecting the ends of the movable arms (9) of the connector when the connector is engaged with the infusion part, and
- a base part (2) which has been reduced to two arms connected to the central part which arms are provided with the retention means (4).

Fig. 6 -11 shows a first embodiment of an injector device (29) which can be used for injection of the infusion part (0B) of the infusion set. In fig. 6 the injector device is separated from the infusion part (0B) and fig. 7 and 8 show the same injector device (29) joined with an infusion part (0B). The injector

device comprises a housing (30) with two longitudinally extending guiding means (31) formed as grooves in this embodiment and a longitudinally slidable member (32) having guiding means (31a), in this embodiment a rim, corresponding to the guiding means (31). A penetrating needle (35) is
5 extending from the front part of the slidable member (32), and the needle (35) is at the end where it is fastened to the slidable member (32) surrounded by guiding means corresponding to the guiding means (13) on the infusion part (0B). The slidable member (32) is capable of moving from a retracted position to a forward position, and is driven from the retracted position to the
10 forward position by a spring (34). The spring is located between the slidable member (32) and the back (33) of the housing. Optionally there is a spring support (37) (fig. 8) which fits with the back of the housing thereby minimizing the risk of a malfunctioning spring. The injector device further comprises locking means (38) for maintaining the spring in a compressed state and
15 release means (39) for disengaging the locking means. When the locking means (38) are disengaged, the spring (34) drives the slidable member (32) to its forward position, thus introducing the cannula positioned at the front end of the infusion part (0B) into the patient by means of the needle (35). After the introduction of the cannula, the injector device including the
20 insertion needle (35) is withdrawn from the infusion part (0B) leaving the insertion needle in an exposed position. The pivoting member (36) can then be swung into a position where it embraces the needle (35) as shown in fig. 9.

25 Fig. 10 and fig. 11 show the same embodiment of the injector device in a loaded and secured position. Part of the pivoting member (36) acts as locking means (38). In Figure 10 it can be seen how the needle (35) fits into the cannula (5) of the infusion part. The needle (35) will bring the cannula (5) with it during the skin penetration. After penetrating the skin the needle (35)
30 secured to the injector will be withdrawn leaving the cannula inserted in the patient. In fig. 11 the locking means are shown said locking means are disengaged when the tab (38) is pushed over the edge of the outer side of the back (33) of the housing.

Figures 12 to 17 show a second embodiment of the injector device according to the invention where the pivoting member (36) is fastened centrally in relation to the slidable member (32). Figure 12 shows the injector device in a state where the pivoting member (36) protects the needle prior to injection of the cannula (5) of the infusion part (0B). The figure shows the housing (30) with another type of longitudinally extending guiding means (31), in this case a bar. The housing further has gripping means (40), preferably in the form of recesses, as means for getting a better grip of the injector device.

10

Centrally positioned release means (39) is shown on one of the main faces of the injector device. The advantage of a one button release mechanism is that the risk of a slanting injection is reduced.

15

In fig. 13 is shown an injector device prepared for insertion of the needle. The pivoting member is positioned away from the embracing position in an angle $v \approx 90^\circ$ in relation to the main axis of the injector device where the main axis is coincident with the insertion needle. The adhesive support (1) is positioned in such manner that the cannula (5) of the infusion part (0B) and the therein positioned needle (35) penetrates the adhesive support through an opening in the release liner. When the pivoting member is positioned essentially perpendicular to the main plane of the injector device it can provide a helping mean for achieving essentially vertical injection of the needle. Further fig. 13 shows the needle (35) of the injector device inside the cannula (5). In fig. 14 the injector device is in a released state where the needle (35) would have penetrated the skin. The housing in the embodiment of fig. 14 has a stopping tab (43) corresponding to a protrusion on the slidable member that keeps the slidable member (32) within the housing (30) thereby making it easier to withdraw the needle since there is no risk that the slidable member slides out of the housing. In fig. 15 the injector device has been withdrawn, leaving the cannula (5) of the infusion part (0B) inserted in the patient. In fig. 16 and 17 the pivoting member (36) is in a position where it embraces the needle (35) thereby protecting the surroundings from coming into contact with the used

20

25

30

needle (35). In fig. 18 the infusion part (0B) has been brought from the essentially vertical insertion position to a position essentially parallel to the skin.

- 5 Fig. 19 shows the injector device together with a credit card to illustrate the size of the injector device.

In fig. 20 is shown a third embodiment of the injector device together with an infusion part (0B). This embodiment also has a housing (30) with
10 longitudinally extending guiding means (31) and a longitudinally slidable member (32) of a different construction compared to the two first embodiments. Also the pivoting arm (36) and the spring (34) can be seen in this figure. In this embodiment the stopping tab (43) is placed centrally and has the form of a protrusion raising from the lower side of the housing (30).
15 The release means (39) comprises two buttons placed on each side of the housing (30).

In fig. 21 A-D it is shown how the infusion part (0B) along with the slidable member (32) and the spring (34) of the third embodiment fit into the housing
20 (30). The unit (?) shown between the pivoting arm (36) and the insertion part (0B) is an adapter which makes it possible to use a standard injector for different guiding means (13) on the infusion part (0B).

In fig. 22 A-B is shown fixing means (44) placed on the pivoting member (36).
25 It is possible to temporarily attach a part of the adhesive support (1) to the fixing means in order to secure the position of the adhesive support in such a way that the adhesive surface of the support (1) will be turned towards the skin of the patient. Further release means (39) in the form of two buttons, one on each side of the housing (30), can be seen as well as the protruding
30 stopping tab (43).

Fig. 23 A-B shows in further details and without the housing how the adhesive support (1) is hooked to the fixing means (44) due to at least one cutting (46) in the adhesive support (1).

- 5 Fig. 24 A shows the third embodiment of the injector device with an infusion part after insertion and 24 B shows the injector device after insertion and after the injector device has been removed from the insertion part (0B).

10 In fig. 25 the pivoting member (36) of the injector device is in a position embracing the needle. A locking tab (45) fixes the pivoting arm in this position. This makes certain that the needle stays embraced by the pivoting arm and thereby minimizes the risk of somebody getting hurt by the needle.

15 Fig. 26 illustrates a third embodiment of an infusion part (0B). The infusion part (0B) comprises a base part (2) which base part (2) comprises a first set of guiding means (13) in the form of two stabilizing fins. The base part (2) comprises two retention devices (4) extending from the upper surface of the base part (2) and having a triangular form. The side of the triangular retention device facing the shoulder part (2a) is approximately perpendicular to the surface of the base part (2) and the side facing away from the shoulder part (2a) is sloping from the top of the retention device (4) to the surface of the base part (2). Mounted on the inner surface of the infusion part (0B) is the adhesive support (1). The cannula (5) is extending from the shoulders (2a) of the base part (2) and is penetrating the adhesive support (1) being in fluid communication with the central cavity (3). The cavity (3) which can be covered by a membrane is adapted to receive a second cannula (6) extending from the connector. In this embodiment the base part (2) has two wide cuttings (12) creating two narrow flaps in the base part (2) on which the retention devices (4) are mounted.

30

The distance between (I) the side of the retention device (4) closest to the central part of the infusion part (0B) and (II) the central part of the infusion part (0B) defines how far it is possible to move the two arms (9) of the

connector in the plane parallel to the base part (2). It is necessary for the corresponding means (10) in the arms (9) of the connector (0A) to be of less width than the distance between (I) and (II). In a preferred embodiment it would also be possible to free the connector (0A) from the infusion part (0B) by moving the arms (9) in a vertical direction away from the base part (2). If this should be possible the arms (9) of the connector need to be adequately flexible where the arms (9) are fixed to the central part of the connector. This can be done either by reducing the thickness of the arms (9) in at least on direction in this area until the desired flexibility is achieved or by choosing to construct the connector part (0A) of a material with a suitable flexibility.

In this embodiment the release liner (41, 42) of the adhesive support (1) is divided into to separated pieces. The first piece (41) is protecting the part of the adhesive support (1) in front of the cannula (5), and the second piece (42) is protecting the part of the adhesive support being behind the cannula (5) and under the infusion part. During insertion the two pieces are separated whereby the part of the adhesive in front of the cannula is bent up and the adhesive side of the adhesive support (1) is exposed around the cannula. The first piece (41) is either pulled back by the user or is attached to one side of the injector device; the second piece (42) is attached to the opposite side of the injector device.

Fig. 35A-E and 36A-E illustrates the cycle of use of the injector device seen respectively from the upper (fig. 35) and the lower (fig. 36) side of the injector device.

In fig. 35A and 36A the device is in a first state, which is the state the device would normally be delivered to the patient in, under sterile conditions. In this state the pivoting arm (36) is in a position where it embraces the needle (35) and the angle ν between the main plane of the injector device and the pivoting arm is approximately 0° , if the release means (39) should unintentionally be pressed in this situation two protruding tabs (48) will prevent the slidable member (32) from being pushed forward.

- In fig. 35B and 36B the device is prepared for use by lifting the pivoting arm (36) backwards thereby exposing the insertion needle (35) and also in this embodiment lifting the part of the release liner (41) which is attached to the pivoting arm (36), exposing the underlying adhesive support (1). In this position the pivoting arm (36) allows for insertion of the needle and is in an angle v to main plane of the injector device where $90^\circ \leq v \leq 180^\circ$, and in this position the injector device would be placed against the patient's skin.
- 10 In fig. 35C and 36C the release means (39) has been pressed and has released the spring (34). The spring has pushed the slidable member (32) forward until the slidable member was stopped by two stopping tabs (43). In this position the insertion needle (35) has penetrated the patient's skin and a part (this part covers an area around the needle in the full breadth of the adhesive support) of the adhesive surface of the adhesive support (1) is in contact with the patient's skin. In fig. 36C it is shown how the second part (42) of the release liner is attached to the housing (30) and still covers the adhesive surface when the slidable member (32) is pushed forward.
- 20 In fig. 35D and 36D it is shown what happens when the injector device is removed from the patient, leaving the infusion part (0B) inserted subcutaneously. The user frees the first part (41) of the release liner from the pivoting arm (36) and then when pulling the injector device away the second part (42) of the release liner is also pulled away, exposing the adhesive surface of the adhesive support (1) and making it possible for the user to press the adhesive support towards the skin and thereby securing the infusion part (0B).
- 25 Finally after withdrawal of the insertion needle which in this embodiment is attached to the slidable member (32) in the injector device, it is shown in fig. 35E and 36E how the pivoting member (36) is placed in a position where it is embracing the needle thereby protecting the surroundings from getting stung. In order to get into this position the pivoting arm (36) is turned approximately
- 30

180° from the position in fig. 35D and 36D, and the angle w between the main plane of the injector device and the pivoting arm (36) is approximately 90°.

PATENT CLAIMS:

1. An infusion set comprising an infusion part (0B) for insertion into a patient and a connector (0A) for connecting the infusion part (0B) with a medical device through a tube (7), the connector being axially displaceable relative to the infusion part, said infusion part comprising an adhesive support (1), a base part (2) with a first set of guiding means (13) and at least two retention devices (4) for locking the connector (0A) to the infusion part (0B), a cannula (5) extending from said base part (2) and being in fluid communication with a cavity (3) which is optionally covered with a membrane, said cavity being further adapted to receive a second cannula (6) extending from the connector, which second cannula (6) is in fluid communication with the tube (7), a second set of guiding means (8) adapted to fit with the first set of guiding means (13) and at least two arms (9), characterized in that the retention devices (4) are extending from the upper surface of the main surface of the base part (2) and that the arms (9) comprise means (10) corresponding to the retention means (4).
2. An infusion set according to claim 1, characterized in that the connector is symmetrical around the main plane of the connector and around the plane perpendicular to the main plane and parallel to the central axis.
3. An infusion set according to claim 1 or 2, characterized in that the connection between each arm (9) and the second set of guiding means (8) is made flexible in order for the arms (9) to be able to move in the direction perpendicular to the base part (2).
4. An infusion set according to claim 3, characterized in that the connection between each arm (9) and the second set of guiding means (8) comprises at least one groove.

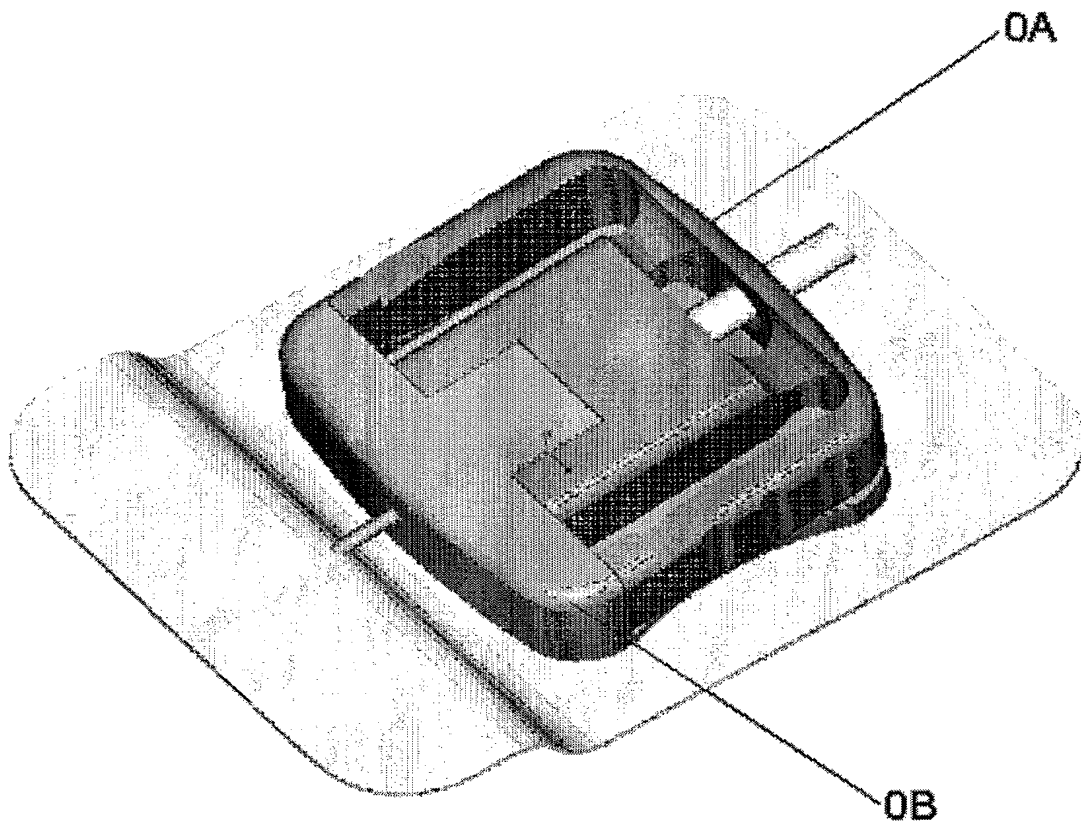
5. An infusion set according to any one of the preceding claims, characterized in that the retention devices (4) are positioned at flexible parts of the base part (2).
- 5 6. An infusion set according to claim 5, characterized in that the base part (2) has at least two cuttings (12) creating at least two flaps on which the retention devices (4) are positioned.
- 10 7. An infusion set according to any one of the preceding claims, characterized in that the cannula (5) passes through the adhesive support (1).
- 15 8. An infusion set according to any one of the preceding claims, characterized in that the adhesive support (1) is a plaster.
- 15 9. An infusion set according to any one of the preceding claims, characterized in that the infusion part (0B) and the connector (0A) are made from two different plastics materials.
- 20 10. An infusion set according to any one of the preceding claims, characterized in that there is a visual difference in the toning of the connector (0A) and the base part (2) of the infusion part (0B).
- 25 11. An infusion set according to any one of the preceding claims, characterized in that the retention devices (4) are in form of a step.
12. An infusion set according to any one of the preceding claims, characterized in that the retention devices (4) have a triangular shape.
- 30 13. An infusion set according to any one of the preceding claims, characterized in that the tube is fastened by means of glue.

14. An infusion set according to any one of the preceding claims, characterized in that the medical device is an insulin pump
15. An infusion set according to any one of the preceding claims,
5 characterized in that the cannula (5) is a soft cannula made of thermoplastic elastomers (TPE).
16. An infusion set according to claim 15, characterized in that the
10 thermoplastic elastomer is selected from the group consisting of polyester ethers, ECDEL, styrene based TPE, olefin based TPE, urethane based TPE, ester based TPE, amid based TPE, polyolefins and silicone rubbers.
17. An infusion set according to claim 15, characterized in that the
15 thermoplastic elastomer is selected from the group consisting of polypropylene, C-FLEX™, mixtures of C-FLEX™ and polypropylene, LUPOLEN™ 1840H, LUPOLEN™ 3020D, PELLETHANE™ 2363-75D, PELLETHANE™ 2363-55D, TECOTHANE™ and CARBOTHANE™
18. An infusion set according to any one of the preceding claims,
20 characterized in that the infusion part (0B) and/or the connector (0A) essentially is made of polypropylene.
19. An infusion set according to claim 1, characterized in that the second
25 cannula (6) is extending from a central part of the connector and is placed in a withdrawn position relative to the front of the central part and that at least one of the first set of guiding means (13) comprises at least two stabilizing fins.
20. An infusion set according to claim 1, comprising an injector device for the
30 subcutaneous introduction of the cannula (5) of the infusion part (0B) into the skin of a patient.

21. An infusion set according to claim 20, characterized in that the injector device comprises a housing (30), a back (33) and longitudinally extending guiding means (31), a member (32) which is longitudinally slidable within the housing (30) and comprising a needle (35) for insertion in the cavity of the cannula (5), a spring (34) located between the back of the housing and the longitudinally slidable member, locking means for maintaining the spring in a compressed state and release means (39) for disengaging the locking means, which device comprises a pivoting member (36) which can be swung from a position in which it allows for insertion of the needle into a position in which it embraces the needle.

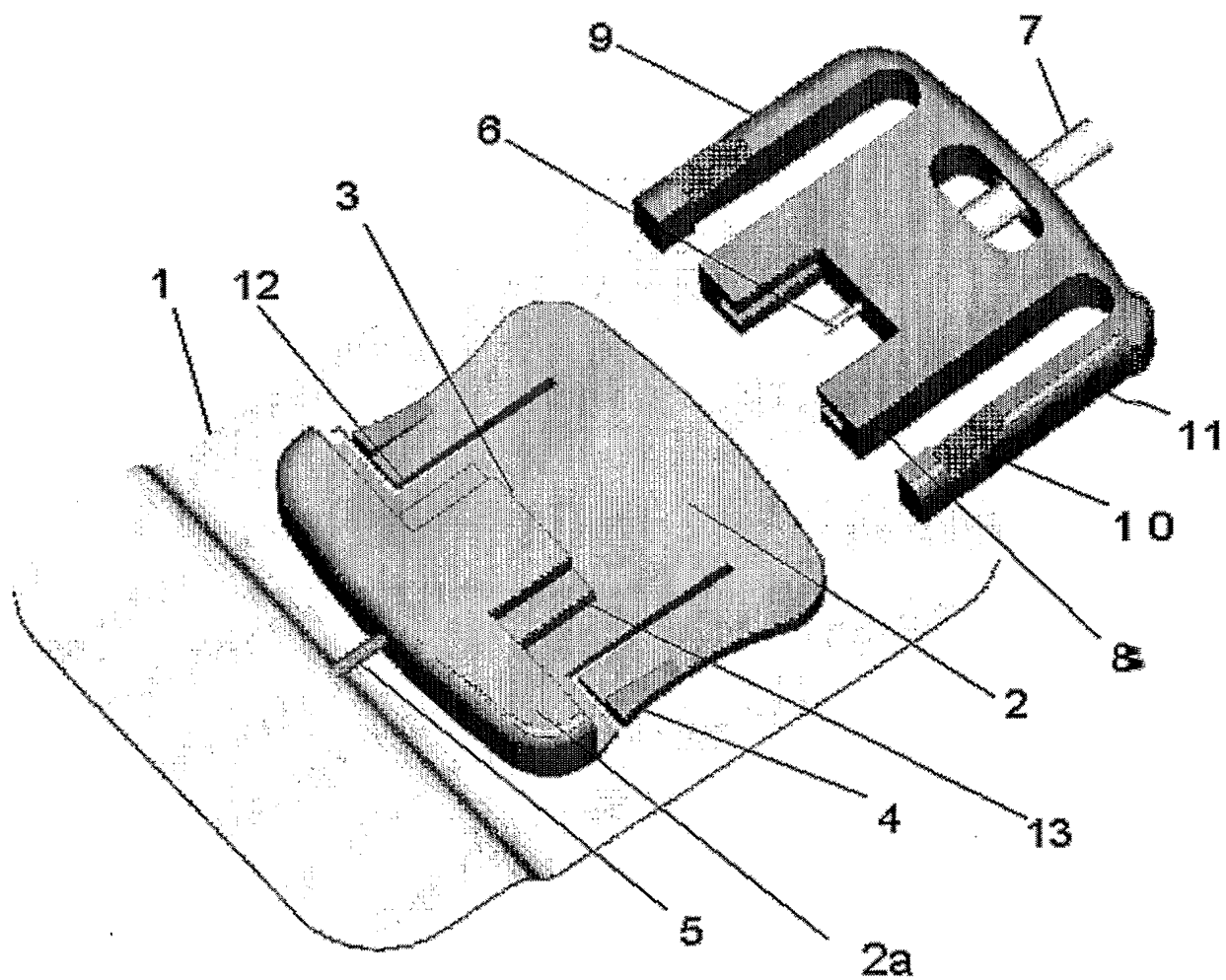
1/27

FIG. 1



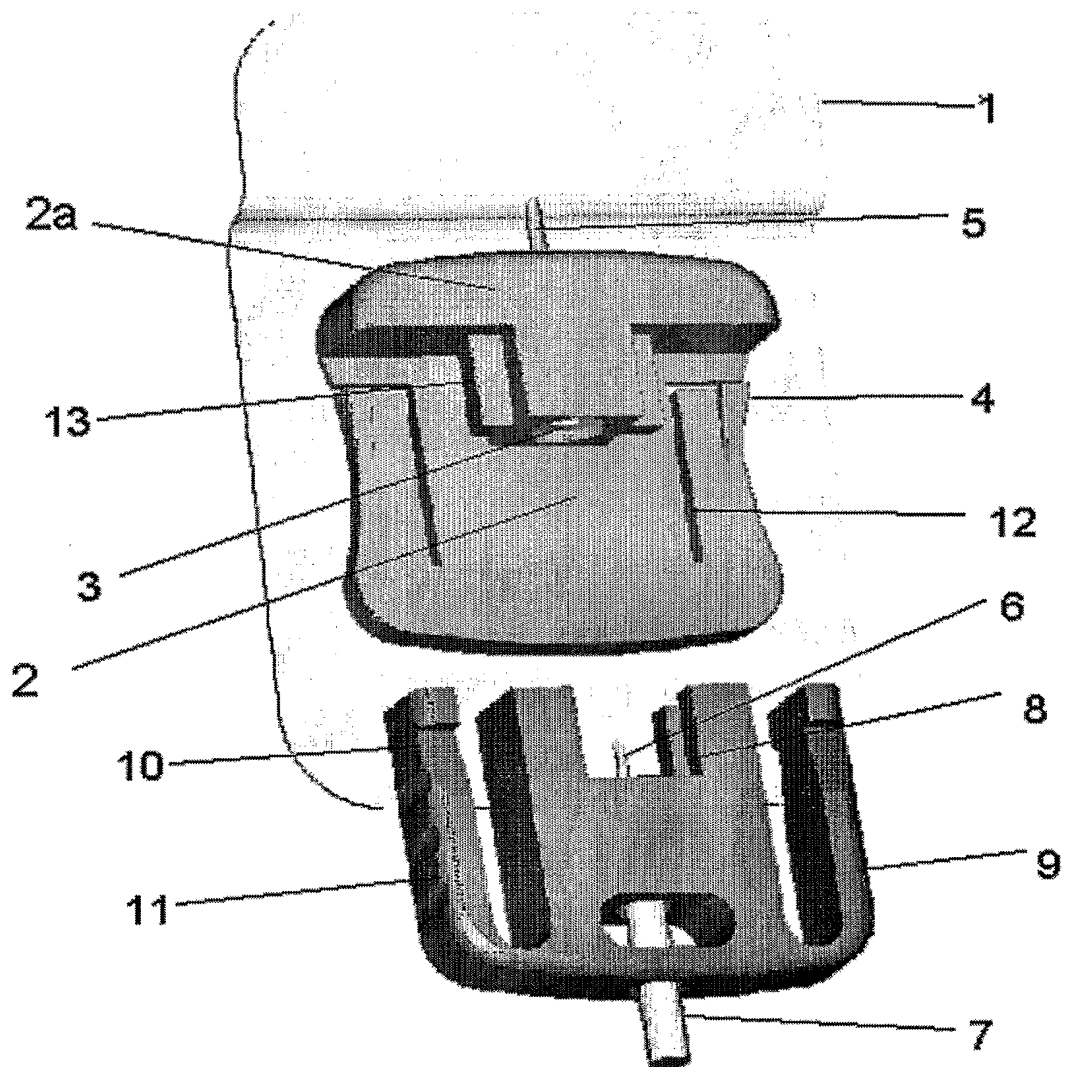
2/27

FIG. 2



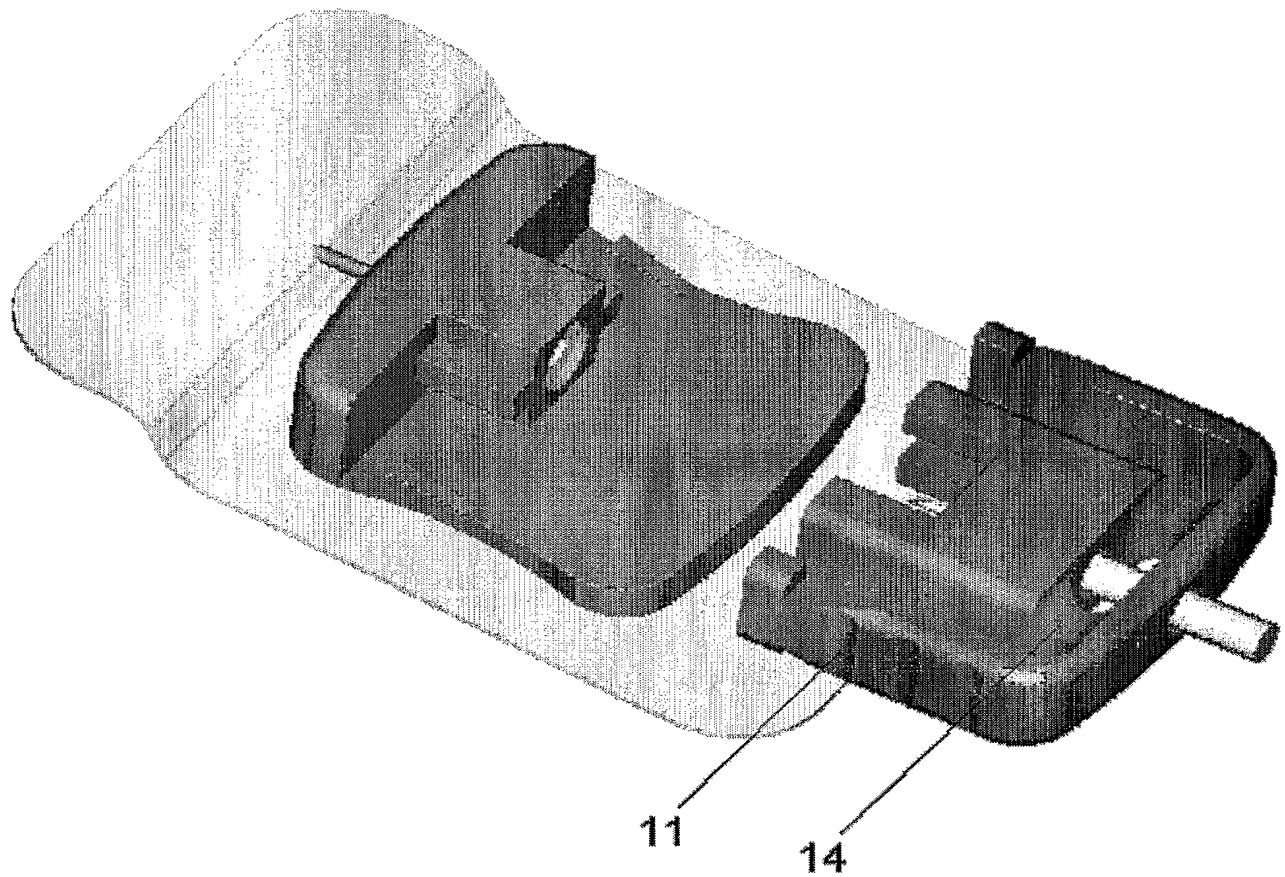
3/27

FIG. 3



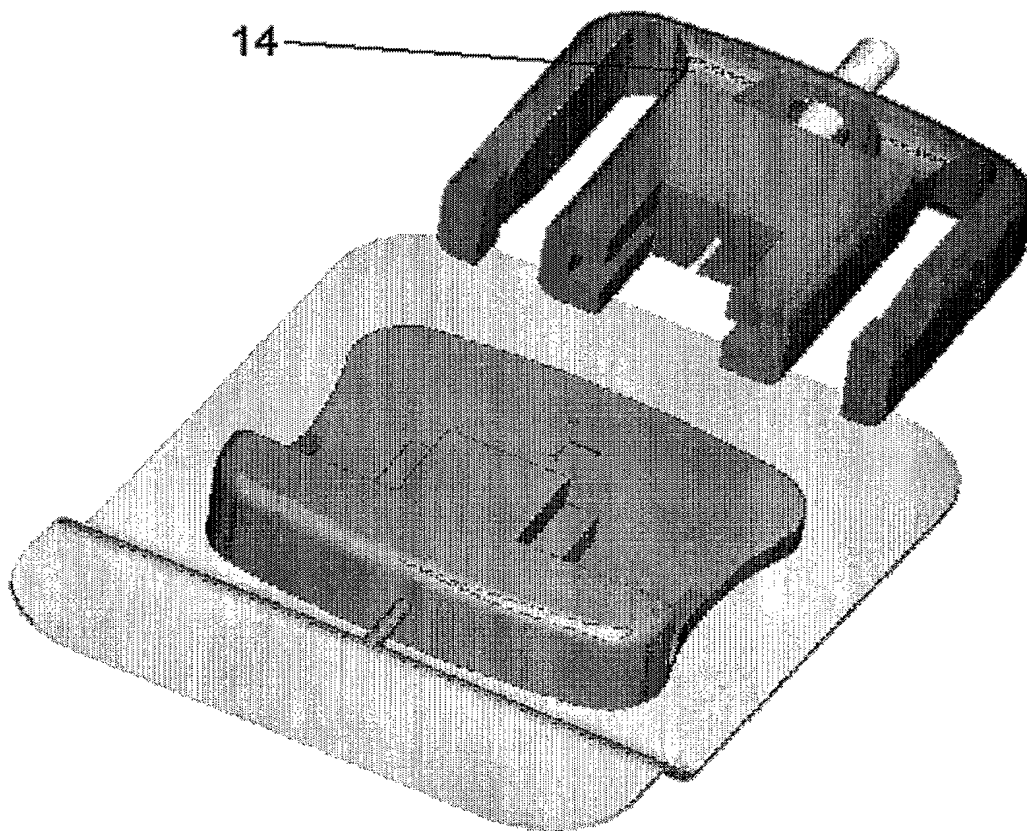
4/27

FIG. 4



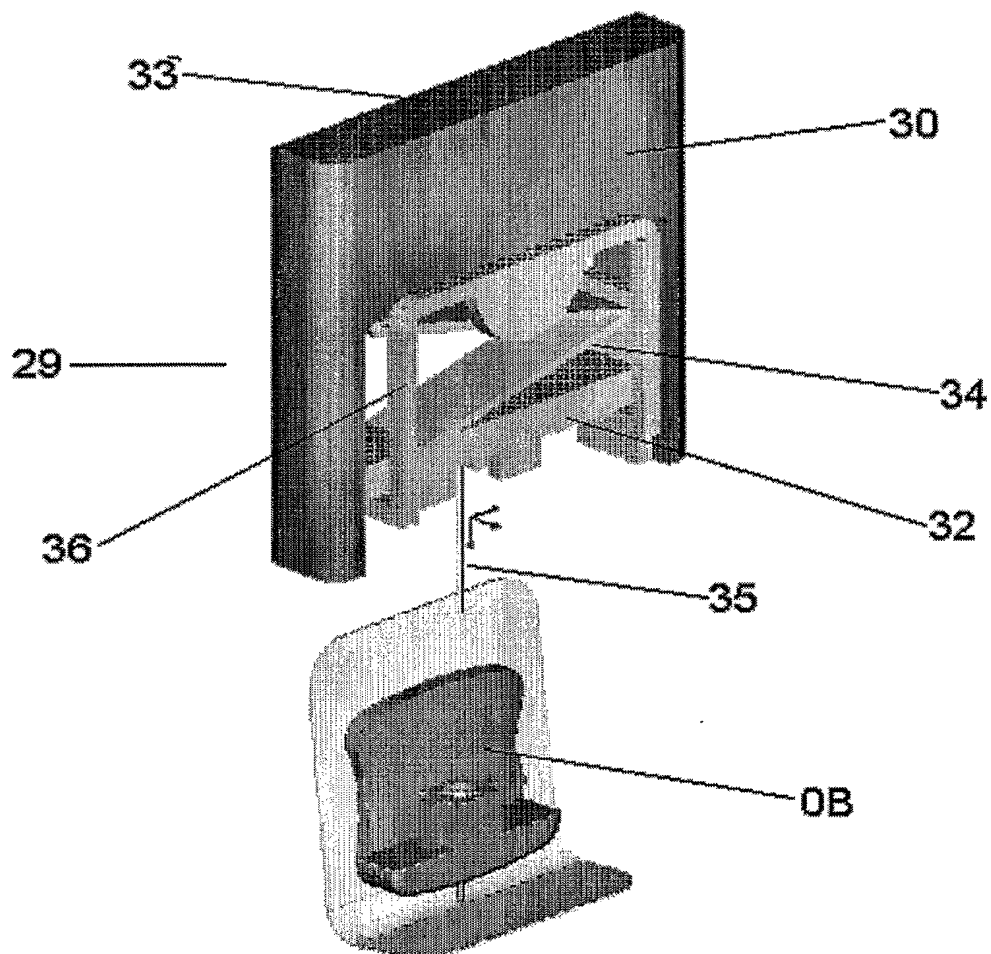
5/27

FIG. 5



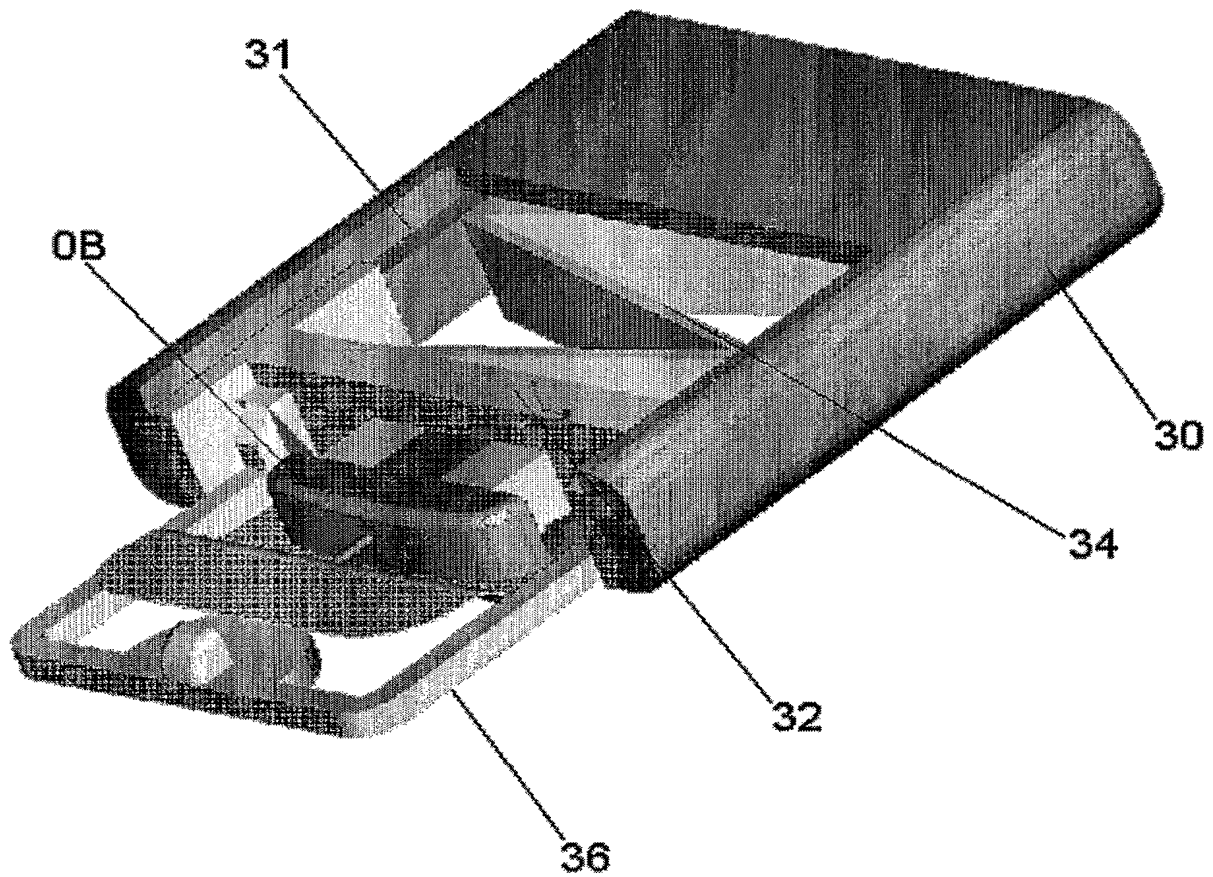
6/27

FIG. 6



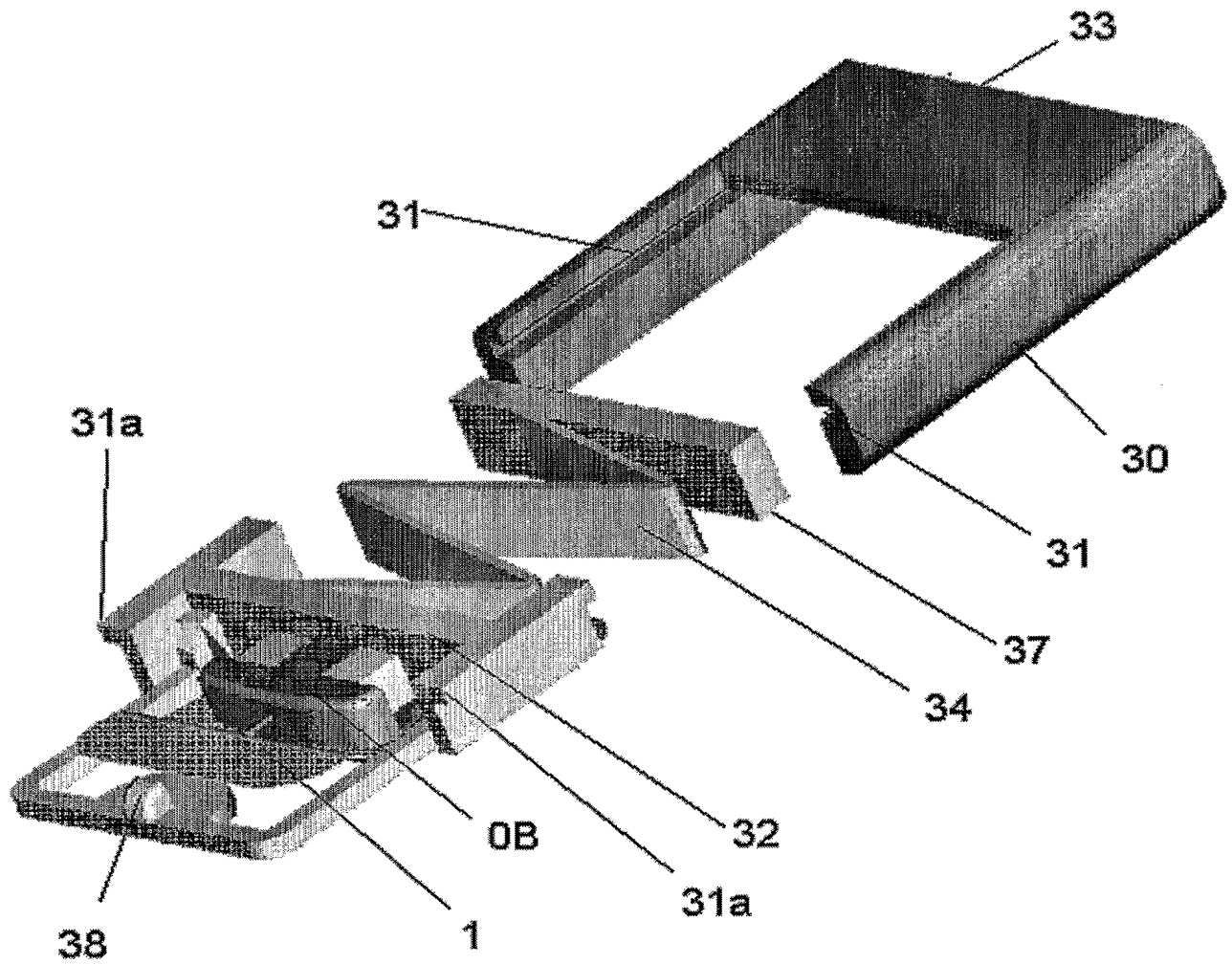
7/27

FIG. 7



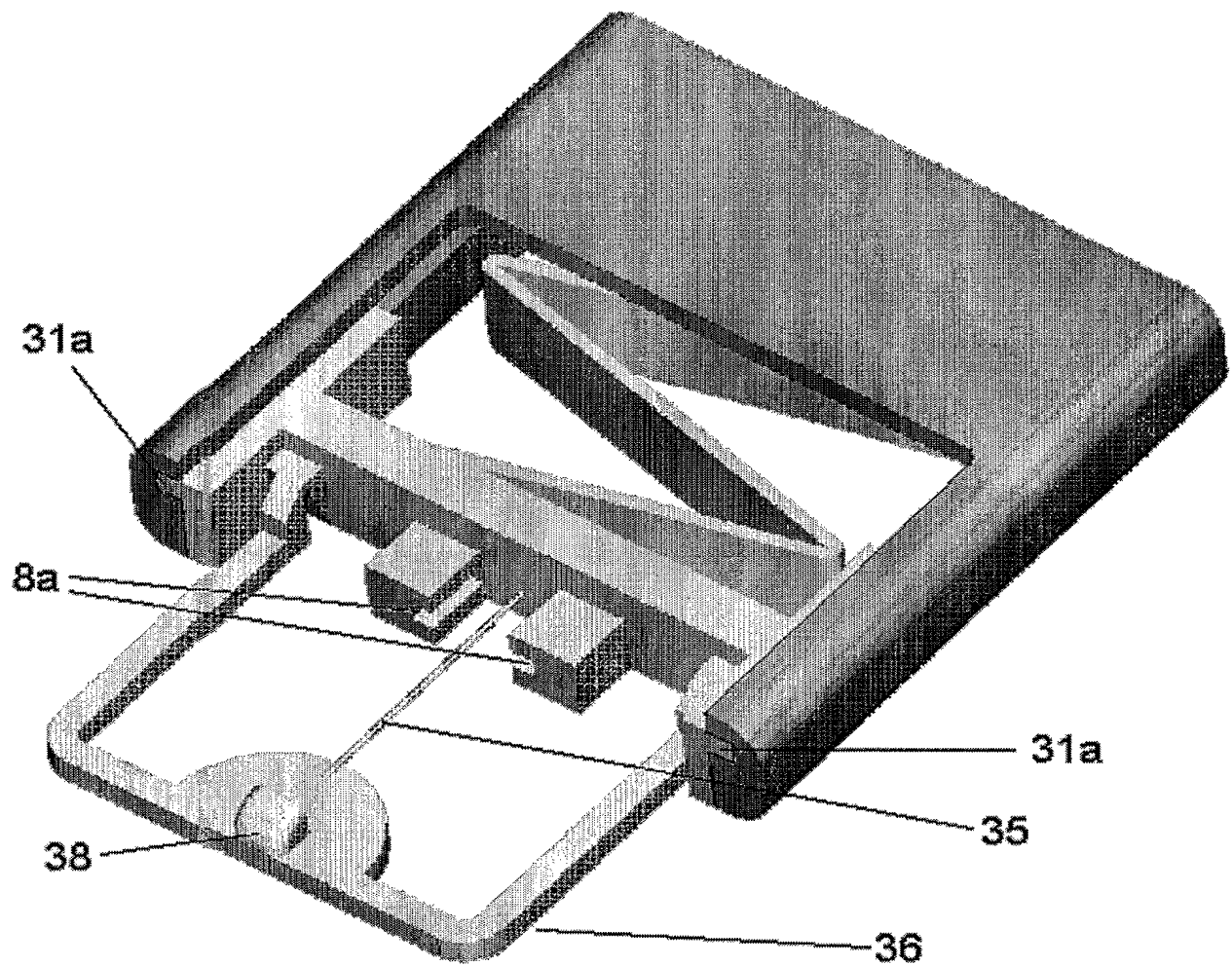
8/27

FIG. 8



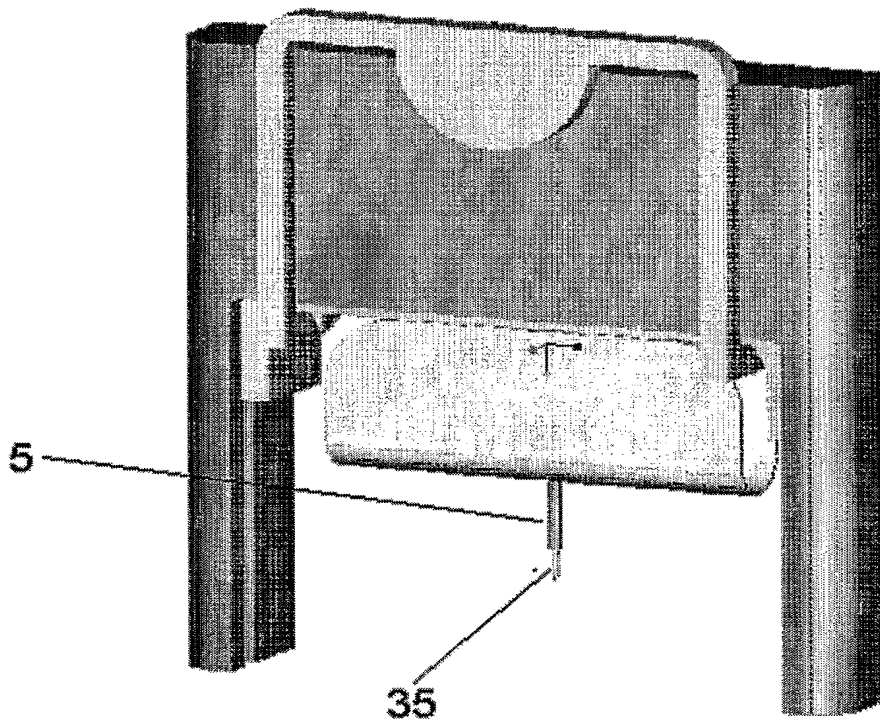
9/27

FIG. 9



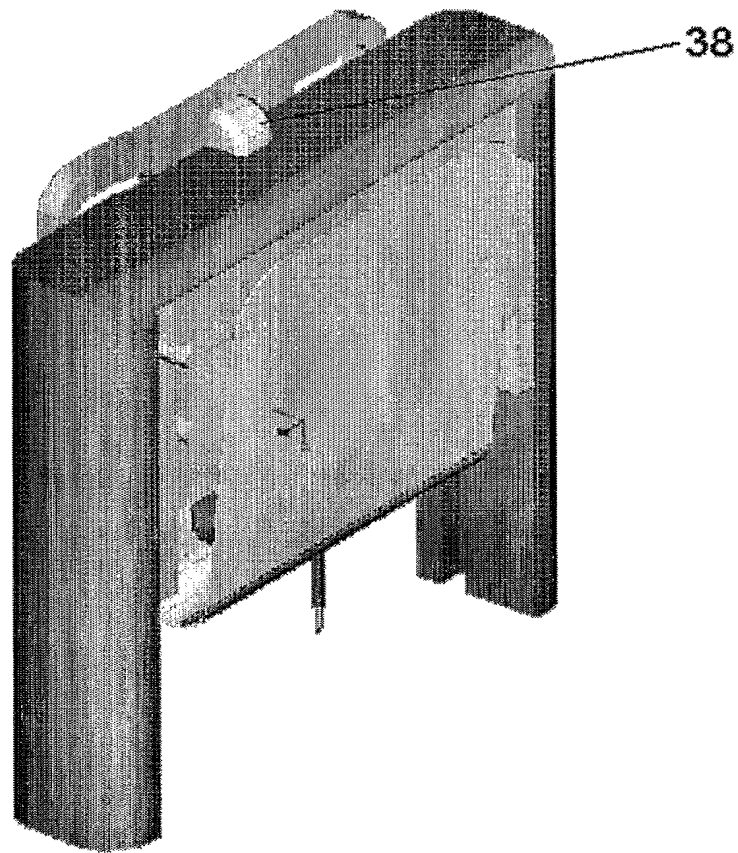
10/27

FIG. 10



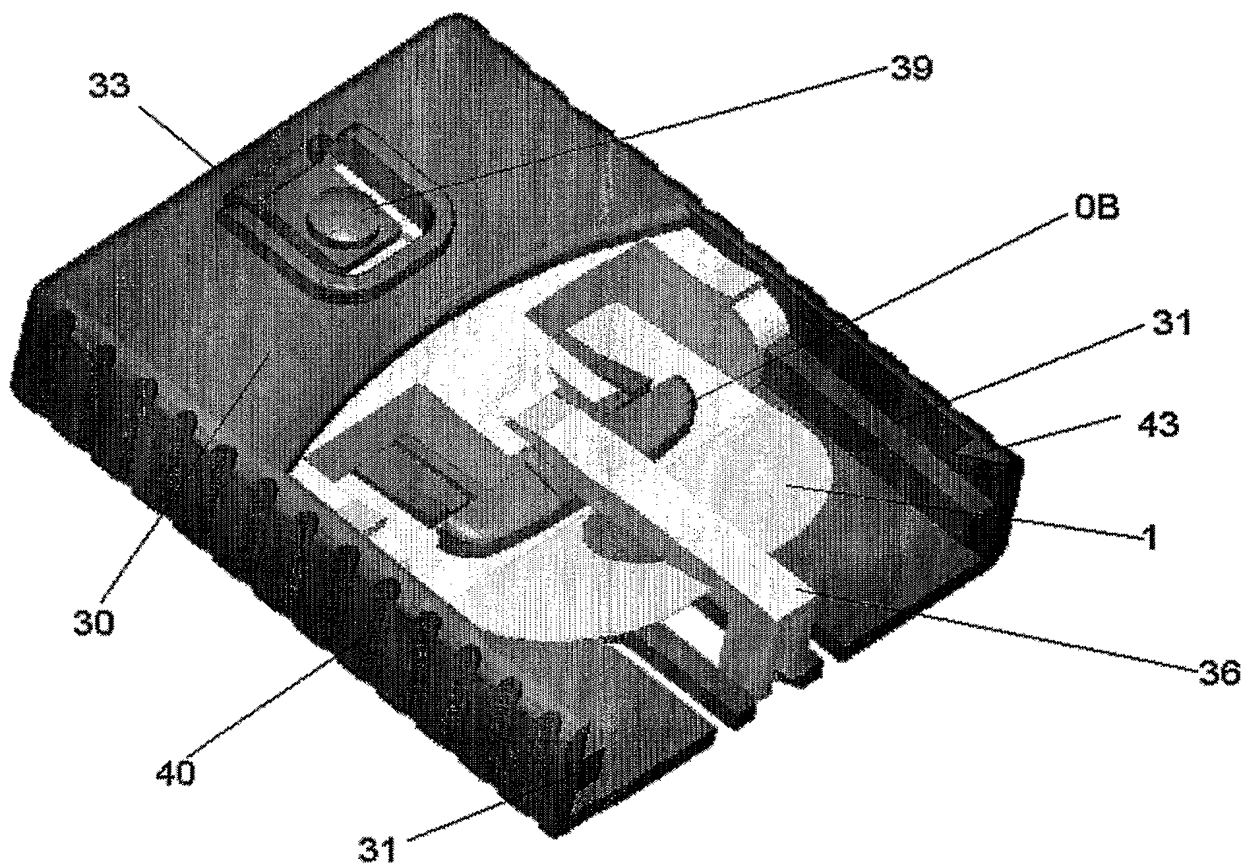
11/27

FIG. 11



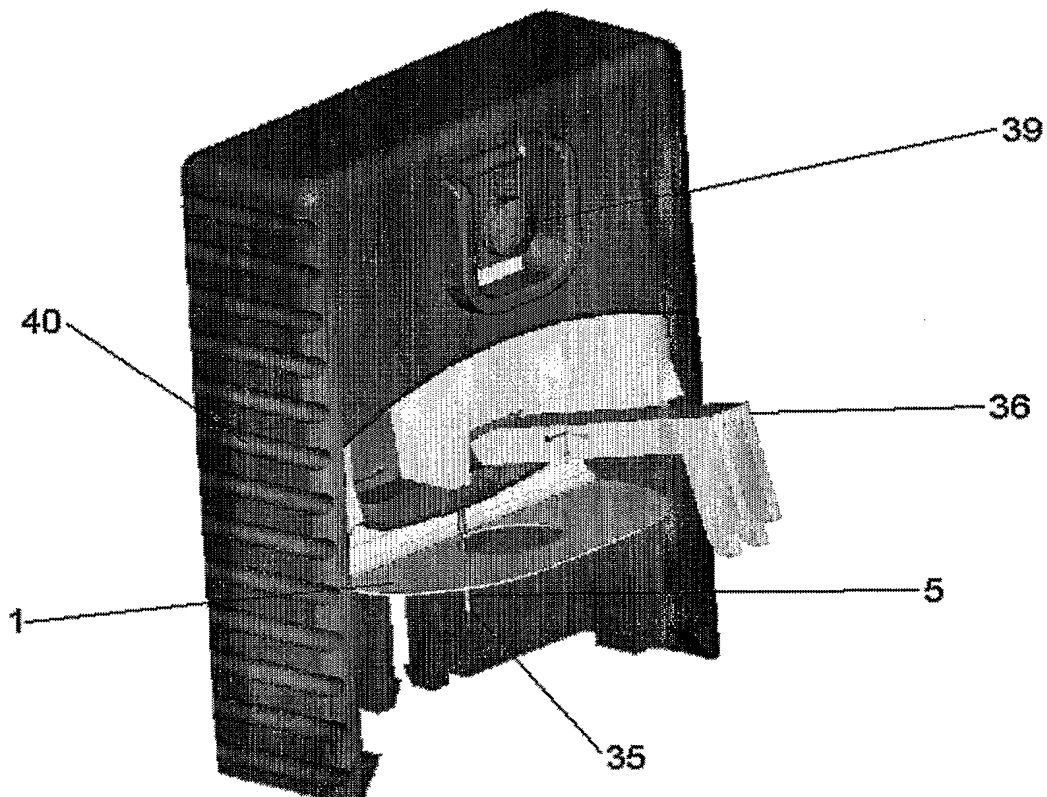
12/27

FIG. 12



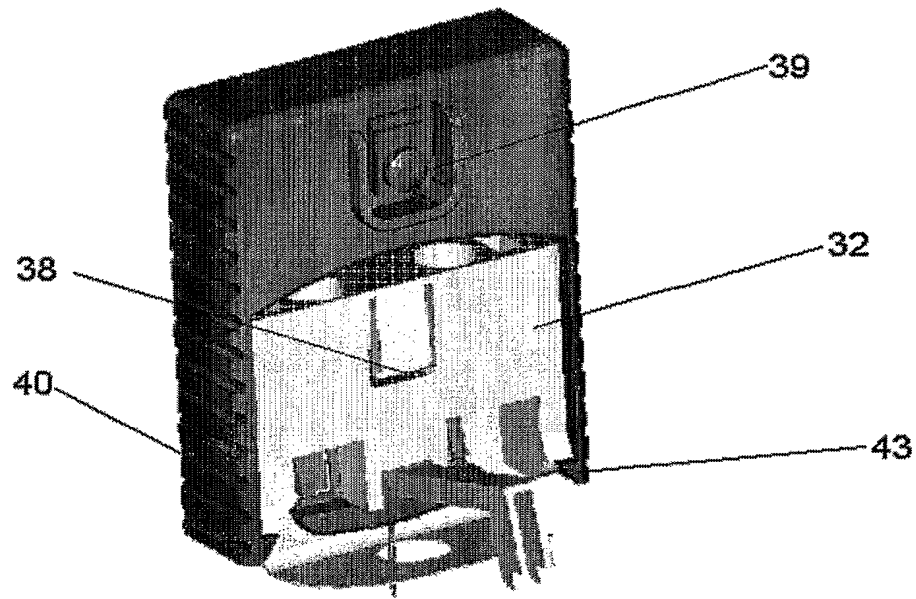
13/27

FIG. 13



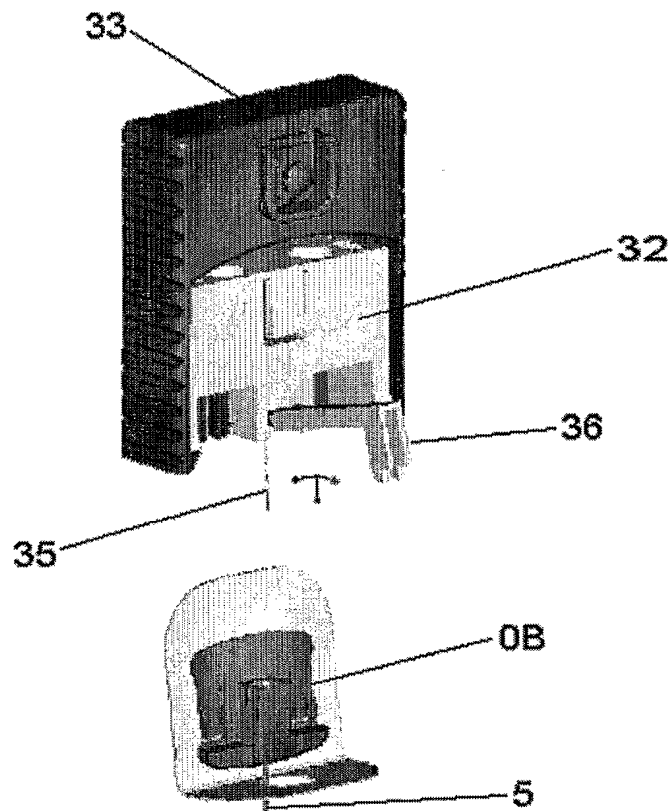
14/27

FIG. 14



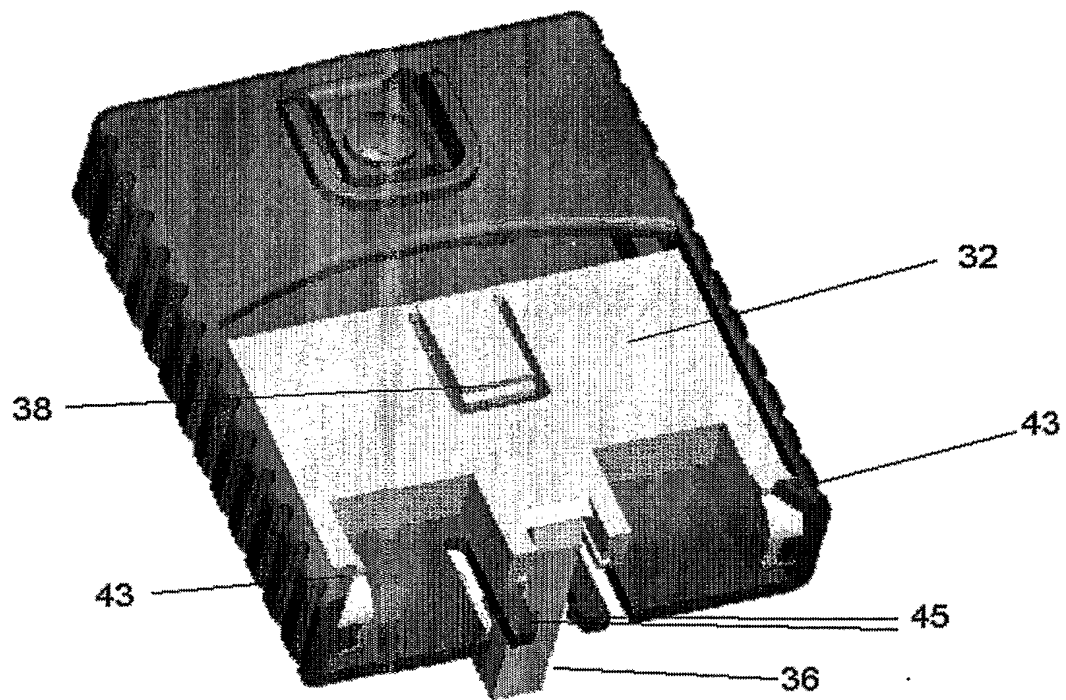
15/27

FIG. 15



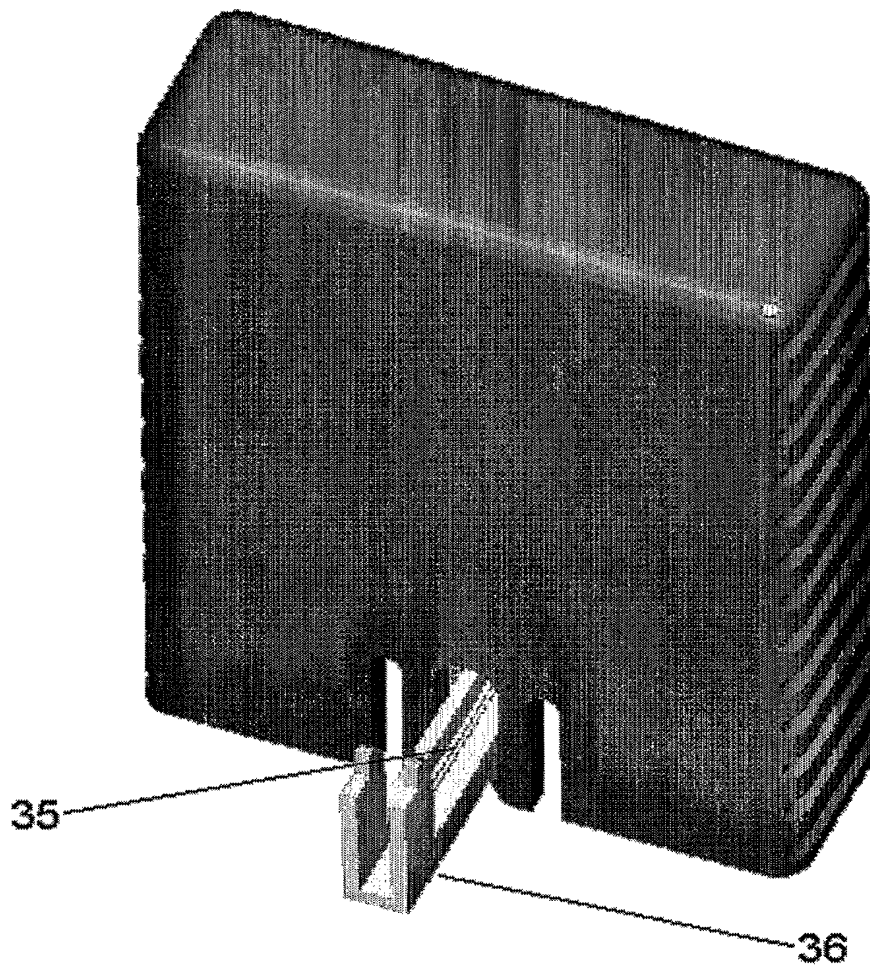
16/27

FIG. 16



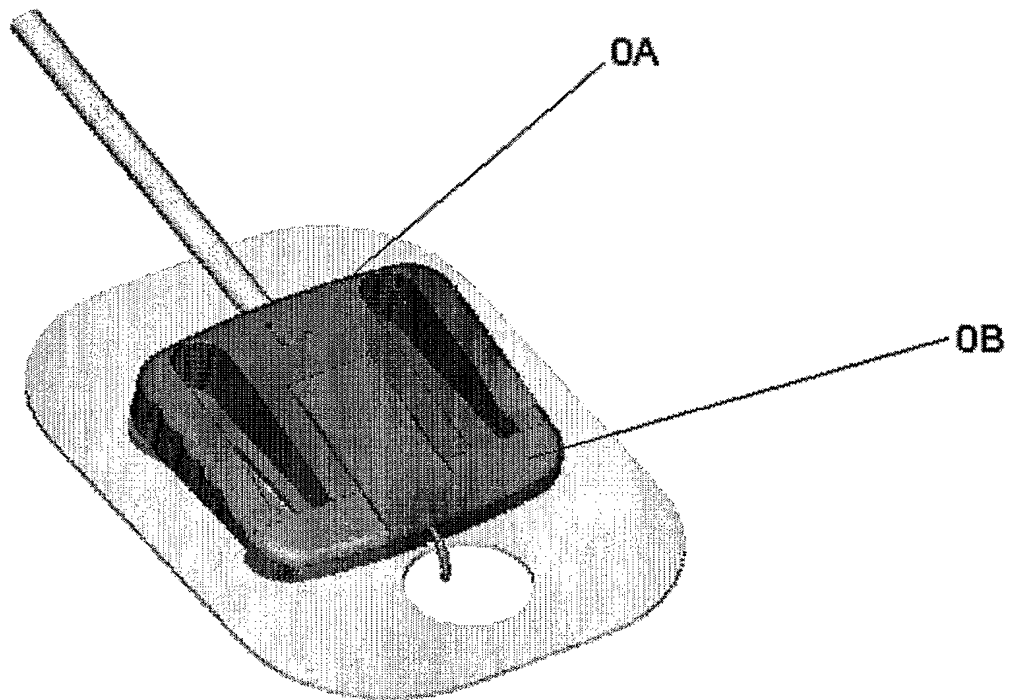
17/27

FIG. 17



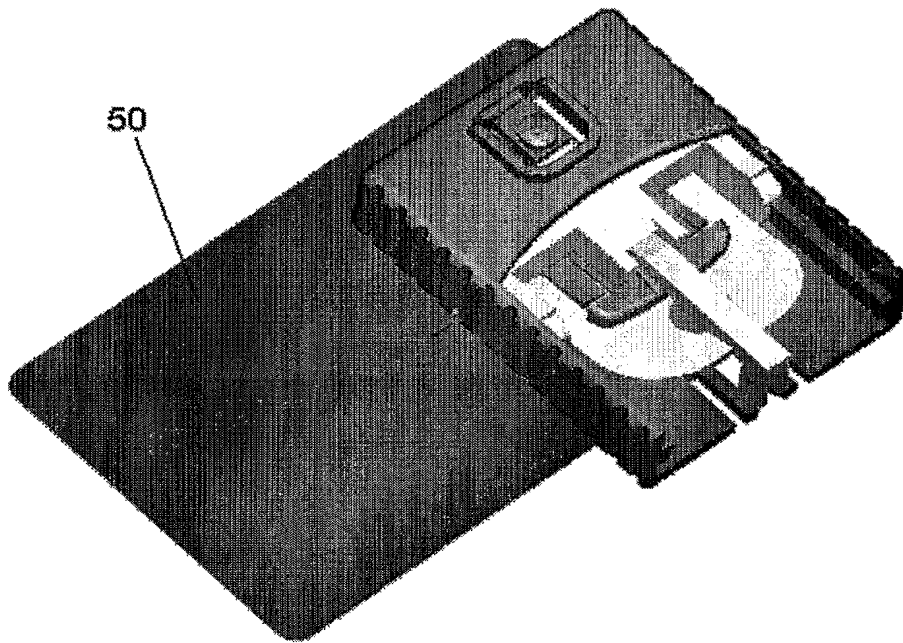
18/27

FIG. 18



19/27

FIG. 19



20/27

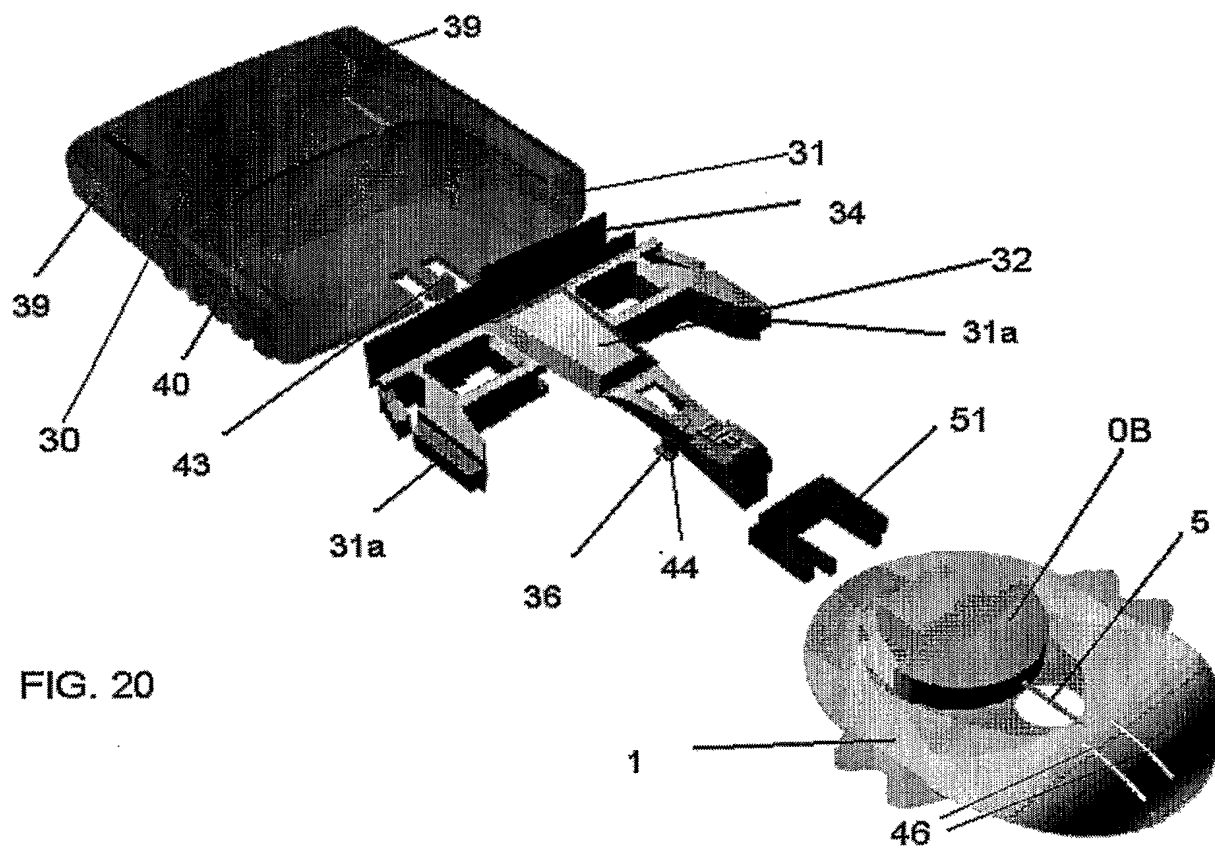
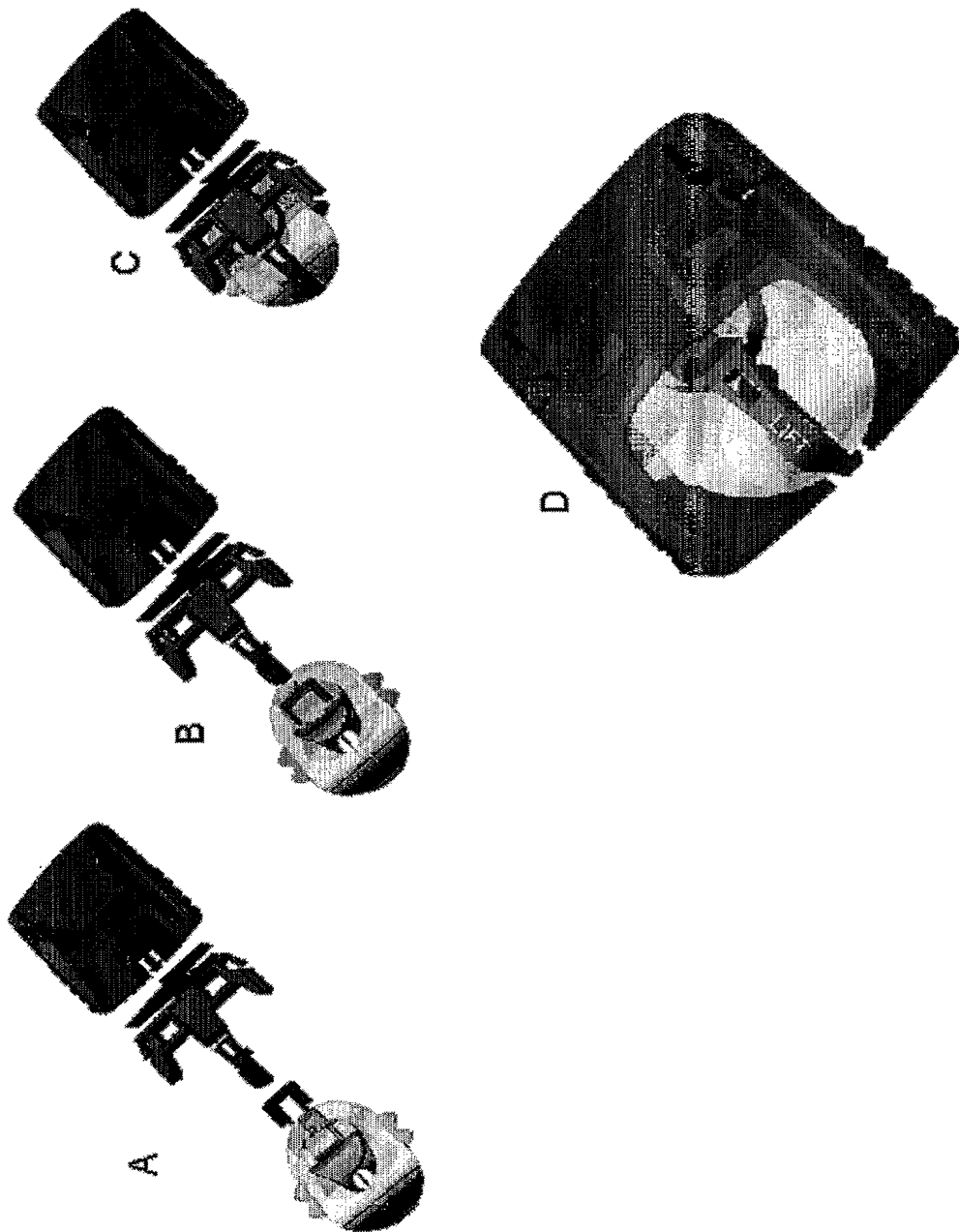


FIG. 20

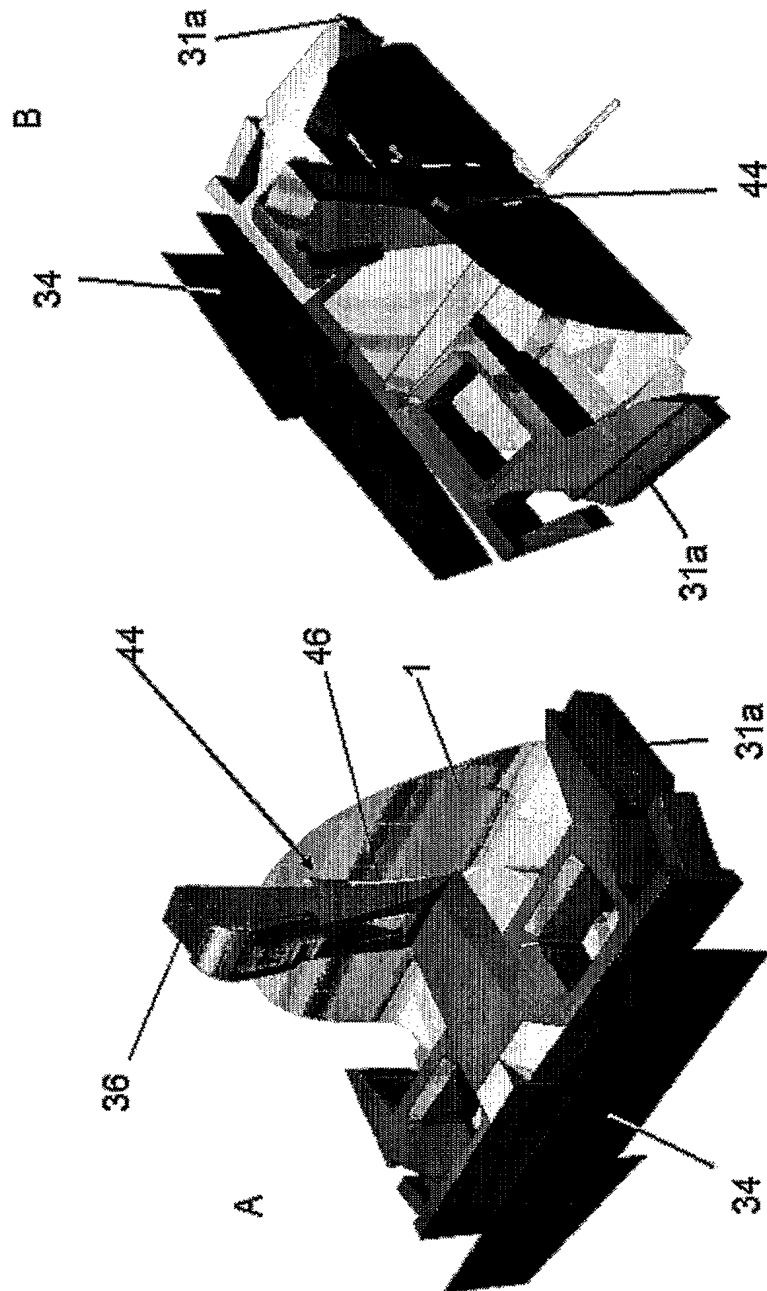
21/27

FIG. 21



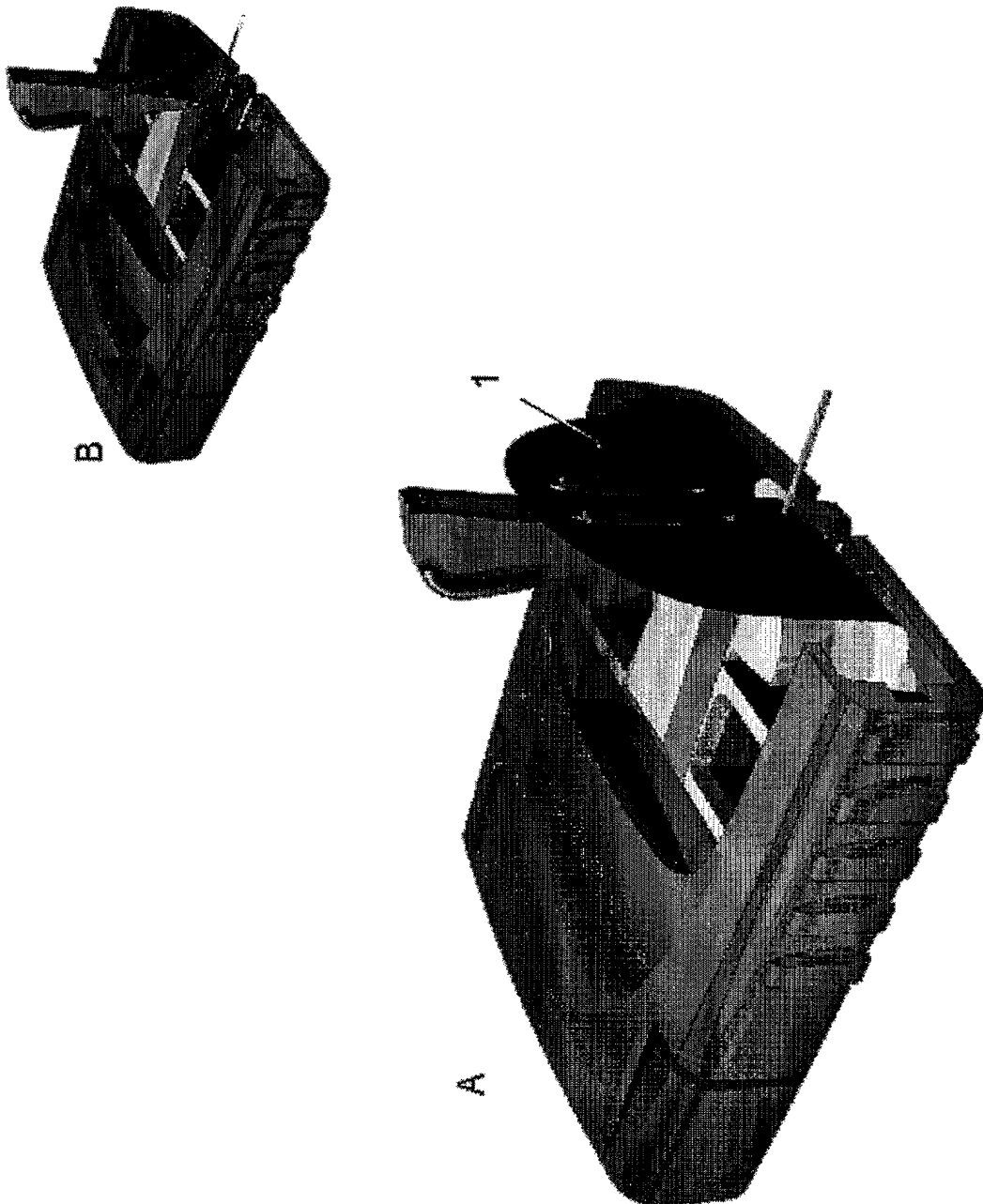
23/27

FIG. 23



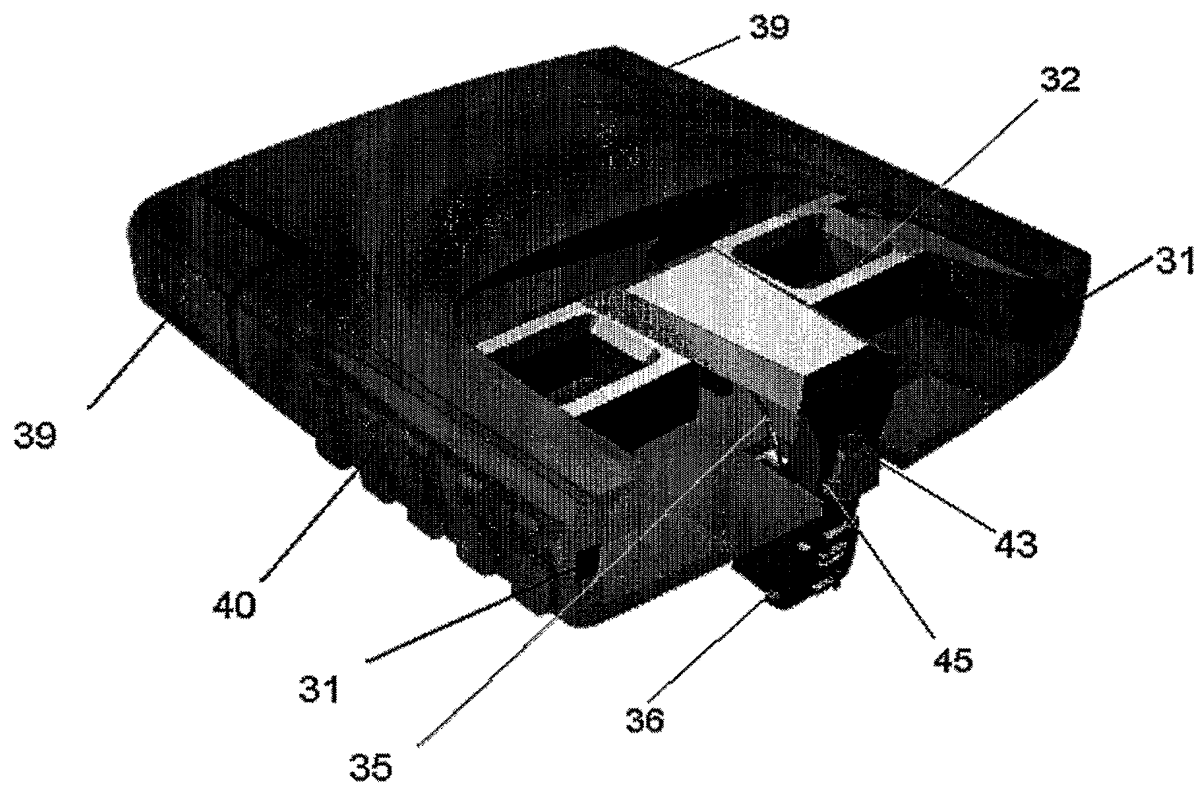
24/27

FIG. 24



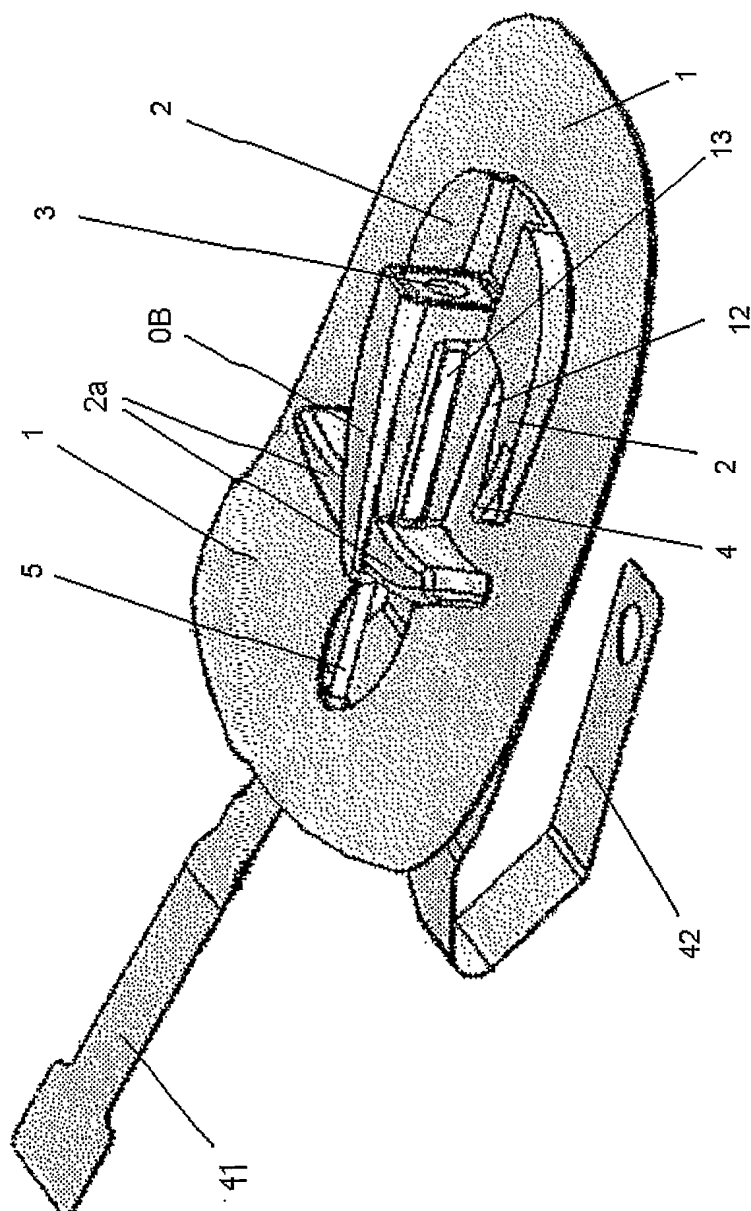
25/27

FIG. 25



26/27

FIG. 26



27/27

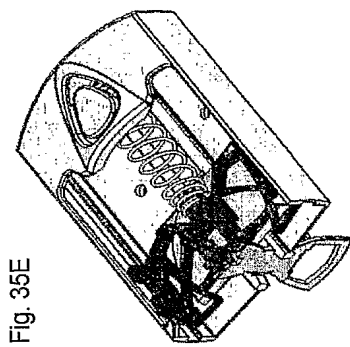


Fig. 35E

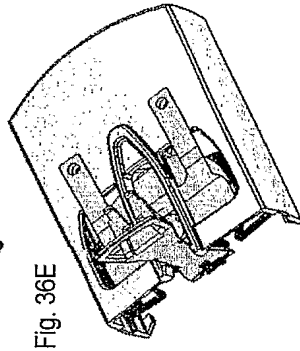


Fig. 36E

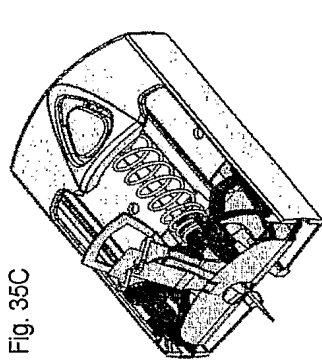


Fig. 35C

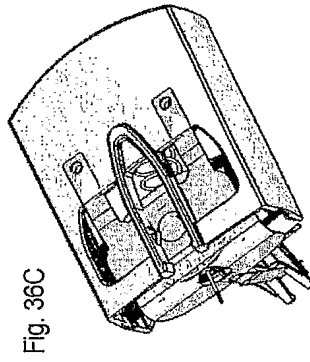


Fig. 36C

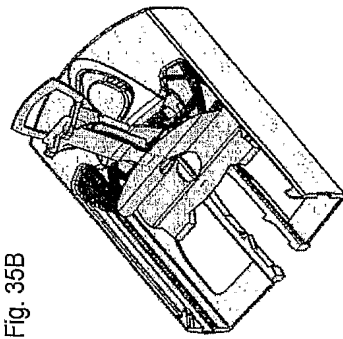


Fig. 35B

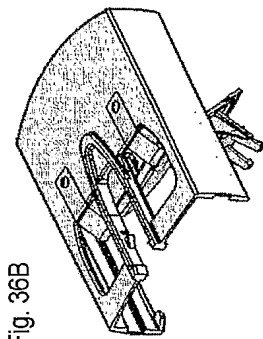


Fig. 36B

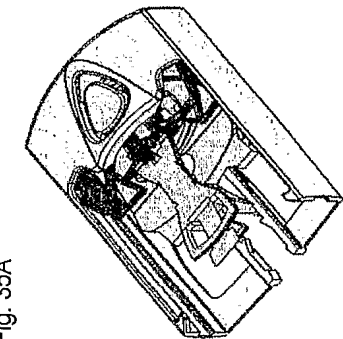


Fig. 35A

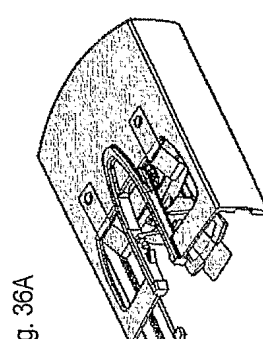


Fig. 36A

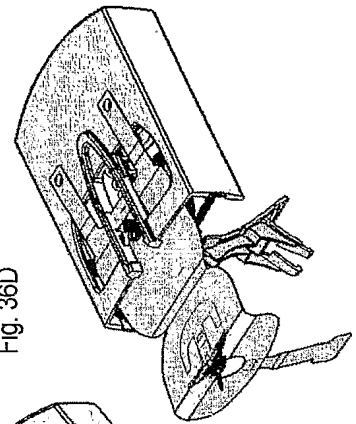


Fig. 36D

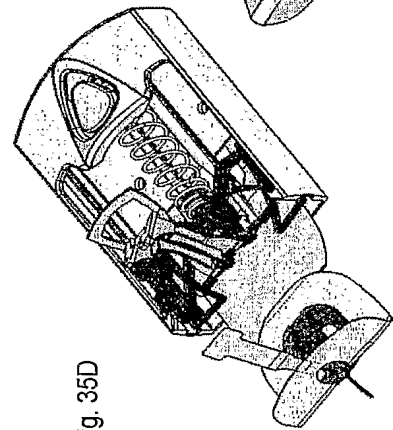


Fig. 35D

INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK2005/000189

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/158

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 572 586 B1 (WOJCIK STEVEN E) 3 June 2003 (2003-06-03) cited in the application	1-19
Y	paragraphs '0049! - '0061!, '0067!, '0068!; figures 1,2,7,11,14,17	20,21
X	US 5 522 803 A (TEISSEN-SIMONY CLAUDE) 4 June 1996 (1996-06-04) cited in the application	1-19
Y	columns 4,16-22 columns 5,28-34 column 5, line 58 - column 6, line 62; figures 1-16	20,21

-/--

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

30 June 2005

Date of mailing of the international search report

27/07/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Krassow, H

INTERNATIONAL SEARCH REPORT

Inte 1al Application No
PCT/DK2005/000189

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/060781 A1 (MOGENSEN LASSE WESSELTOFT ET AL) 27 March 2003 (2003-03-27) paragraphs '0006!, '0007!, '0048! - '0054!; figures 13-16 -----	20,21
A	US 6 293 925 B1 (SAFABASH JASON H ET AL) 25 September 2001 (2001-09-25) figures 1-49 -----	20,21
A	US 6 123 690 A (MEJSLOV JESPER) 26 September 2000 (2000-09-26) figures 1-8 -----	1-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte [REDACTED] I Application No
PCT/DK2005/000189

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6572586	B1	03-06-2003	AU 7031701 A CA 2417183 A1 EP 1305068 A1 JP 2004504116 T WO 0207804 A1	05-02-2002 31-01-2002 02-05-2003 12-02-2004 31-01-2002
US 5522803	A	04-06-1996	DK 25793 A AU 673903 B2 AU 6256794 A CA 2157676 A1 DE 69415658 D1 DE 69415658 T2 WO 9420160 A1 DK 688232 T3 EP 0688232 A1 ES 2126744 T3 FI 954228 A JP 3353229 B2 JP 8507235 T NO 953549 A RU 2131747 C1	10-09-1994 28-11-1996 26-09-1994 15-09-1994 11-02-1999 17-06-1999 15-09-1994 30-08-1999 27-12-1995 01-04-1999 08-09-1995 03-12-2002 06-08-1996 08-09-1995 20-06-1999
US 2003060781	A1	27-03-2003	US 2003109829 A1 BR 0212859 A CA 2460637 A1 CN 1558782 A WO 03026728 A1 EP 1429826 A1 JP 2005503243 T US 2005124936 A1 US 2005043687 A1 US 2004204687 A1	12-06-2003 13-10-2004 03-04-2003 29-12-2004 03-04-2003 23-06-2004 03-02-2005 09-06-2005 24-02-2005 14-10-2004
US 6293925	B1	25-09-2001	US 6093172 A CA 2312919 A1 CA 2484271 A1 JP 2003527138 T WO 9933504 A1 US 2004002682 A1 US 2003158520 A1 US 2003130619 A1 US 2003125669 A1 US 2003225373 A1 US 2003199823 A1 US 2002022855 A1 EP 1044028 A1	25-07-2000 08-07-1999 08-07-1999 16-09-2003 08-07-1999 01-01-2004 21-08-2003 10-07-2003 03-07-2003 04-12-2003 23-10-2003 21-02-2002 18-10-2000
US 6123690	A	26-09-2000	DE 29905066 U1	09-09-1999